Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review)


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**CONTRIBUTIONS OF AUTHORS**

**DECLARATIONS OF INTEREST**

**SOURCES OF SUPPORT**

**DIFFERENCES BETWEEN PROTOCOL AND REVIEW**

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Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review)

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Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

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ABSTRACT

Background
Fetal compromise in the term pregnancy is suspected when the following clinical indicators are present: intrauterine growth restriction (IUGR), decreased fetal movement (DFM), or when investigations such as cardiotocography (CTG) and ultrasound reveal results inconsistent with standard measurements. Pathological results would necessitate the need for immediate delivery, but the management for ‘suspicious’ results remains unclear and varies widely across clinical centres. There is clinical uncertainty as to how to best manage women presenting with a suspected term compromised baby in an otherwise healthy pregnancy.

Objectives
To assess, using the best available evidence, the effects of immediate delivery versus expectant management of the term suspected compromised baby on neonatal, maternal and long-term outcomes.

Search methods
We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register (31 May 2015) and reference lists of retrieved studies.

Selection criteria
Randomised or quasi-randomised controlled trials comparing expectant management versus planned early delivery for women with a suspected compromised fetus from 37 weeks’ gestation or more.

Data collection and analysis
Two review authors independently assessed trials for inclusion and assessed trial quality. Two review authors independently extracted data. Data were checked for accuracy. We assessed the quality of the evidence using the GRADE approach.
Main results

Of the 20 reports identified by the search strategy, we included three trials (546 participants: 269 to early delivery and 277 to expectant management), which met our inclusion criteria. Two of the trials compared outcomes in 492 pregnancies with IUGR of the fetus, and one in 54 pregnancies with oligohydramnios. All three trials were of reasonable quality and at low risk of bias. The level of evidence was graded moderate, low or very low, downgrading mostly for imprecision and for some indirectness. Overall, there was no difference in the primary neonatal outcomes of perinatal mortality (no deaths in either group, one trial, 459 women, evidence graded moderate), major neonatal morbidity (risk ratio (RR) 0.15, 95% confidence interval (CI) 0.01 to 2.81, one trial, 459 women, evidence graded low), or neurodevelopmental disability/impairment at two years of age (RR 2.04, 95% CI 0.62 to 6.69, one trial, 459 women, evidence graded low). There was no difference in the risk of necrotising enterocolitis (one trial, 333 infants) or meconium aspiration (one trial, 459 infants). There was also no difference in the reported primary maternal outcomes: maternal mortality (RR 3.07, 95% CI 0.13 to 74.87, one trial, 459 women, evidence graded low), and significant maternal morbidity (RR 0.92, 95% CI 0.38 to 2.22, one trial, 459 women, evidence graded low).

The gestational age at birth was on average 10 days earlier in women randomised to early delivery (mean difference (MD) -9.50, 95% CI -10.82 to -8.18, one trial, 459 women) and women in the early delivery group were significantly less likely to have a baby beyond 40 weeks’ gestation (RR 0.10, 95% CI 0.01 to 0.67, one trial, 33 women). Significantly more infants in the planned early delivery group were admitted to intermediate care nursery (RR 1.28, 95% CI 1.02 to 1.61, two trials, 491 infants). There was no difference in the risk of respiratory distress syndrome, (one trial, 333 infants), Apgar score less than seven at five minutes (three trials, 546 infants), resuscitation required (one trial, 459 infants), mechanical ventilation (one trial, 337 infants), admission to neonatal intensive care unit (NICU) (RR 0.88, 95% CI 0.35 to 2.23, three trials, 545 infants, evidence graded very low), length of stay in NICU/SCN (one trial, 459 infants), and sepsis (two trials, 366 infants).

Babies in the expectant management group were more likely to be < 2.3rd centile for birthweight (RR 0.51, 95% CI 0.36 to 0.73, two trials, 491 infants), however there was no difference in the proportion of babies with birthweight < 10th centile (RR 0.98, 95% CI 0.88 to 1.10). There was no difference in any of the reported maternal secondary outcomes including: caesarean section rates (RR 1.02, 95% CI 0.65 to 1.59, three trials, 546 women, evidence graded low), placental abruption (one trial, 459 women), pre-eclampsia (one trial, 459 women), vaginal birth (three trials 546 women), assisted vaginal birth (three trials 546 women), breastfeeding rates (one trial, 218 women), and number of weeks of breastfeeding after delivery one trial, 124 women). There was an expected increase in induction in the early delivery group (RR 2.05, 95% CI 1.78 to 2.37, one trial, 459 women).

No data were reported for the pre-specified secondary neonatal outcomes of the number of days of mechanical ventilation, moderate-severe hypoxic ischaemic encephalopathy or need for therapeutic hypothermia. Likewise, no data were reported for secondary maternal outcomes of postnatal infection, maternal satisfaction or views of care.

Authors’ conclusions

A policy for planned early delivery versus expectant management for a suspected compromised fetus at term does not demonstrate any differences in major outcomes of perinatal mortality, significant neonatal or maternal morbidity or neurodevelopmental disability. In women randomised to planned early delivery, the gestational age at birth was on average 10 days earlier, women were less likely to have a baby beyond 40 weeks’ gestation, they were more likely to be induced and infants were more likely to be admitted to intermediate care nursery. There was also a significant difference in the proportion of babies with a birthweight centile < 2.3rd, however this did not translate into a reduction in morbidity. The review is informed by only one large trial and two smaller trials assessing fetuses with IUGR or oligohydramnios and therefore cannot be generalised to all term pregnancies with suspected fetal compromise. There are other indications for suspecting compromise in a fetus at or near term such as maternal perception of DFM, and ultrasound and/or CTG abnormalities. Future randomised trials need to assess effectiveness of timing of delivery for these indications.

Plain language summary

Immediate delivery or expectant management of the term baby with suspected fetal compromise for improving pregnancy outcomes

For healthy pregnant women at term, several factors can indicate that the baby’s health is at risk. These may be based on either clinical examination or history. Babies not growing appropriately (intrauterine growth restriction) or showing a decrease in their movements may indicate the placenta is not functioning as well as it should, while investigations such as cardiotocography (CTG) and ultrasound...
can measure amniotic fluid, blood flow or the size of the baby in order to assess the baby’s well-being. Results that are clearly abnormal and associated with increased risk for the baby require immediate delivery, but the management for ‘suspicious’ results remains unclear and varies widely across clinical centres. The balance between allowing the pregnancy to continue for full lung development has to be weighed against removing the baby from an environment that is suspected to be harmful. The best timing of delivery for women presenting with a suspected compromised baby in an otherwise healthy term pregnancy is unclear.

We identified three randomised controlled trials that met our inclusion criteria. They included a total of 546 pregnant women at 37 weeks gestation or more; 269 had a planned early delivery and 277 were managed expectantly. Two of the trials compared outcomes in a total of 492 babies with growth restriction and one involved 54 pregnancies with decreased amniotic fluid (oligohydramnios). Overall, there were no major differences between these two strategies as to whether infants survived, were extremely sick, or had developmental problems as children. There were also no differences as to whether mothers died or were extremely unwell. The risks of breathing difficulty, poor condition at birth, admission to neonatal intensive care unit, infection, and babies with low blood sugars were no different between the two groups. The gestational age at birth was on average 10 days earlier in women randomised to early delivery and more infants in the planned early delivery group were admitted to intermediate care nursery. Although there was no difference in the number of babies with birthweight less than the 10th percentile between the two groups, there were more extremely small babies (< 2.3rd percentile) found in the expectant management group. Women in the early delivery group were more likely to be induced. All three trials were of reasonable quality and at low risk of bias.

In summary, there is insufficient evidence from randomised trials to guide clinical practice regarding earlier delivery versus waiting for term pregnancies where there is a suspicion of fetal compromise. Included trials only addressed growth restriction or oligohydramnios and none of the other potential indications such as decreased fetal movements, ultrasound or CTG abnormalities. Further research is needed to assess the best timing of delivery for these indications.
### Summary of Findings for the Main Comparison

Planned early delivery compared with expectant management for improving outcomes of the term suspected compromised baby

**Patient or population:** pregnant women with a term suspected compromised baby  
**Settings:** studies took place in The Netherlands and Sweden  
**Intervention:** planned early delivery  
**Comparison:** expectant management

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
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<tr>
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<td>Assumed risk</td>
<td>Corresponding risk</td>
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<tr>
<td><strong>Perinatal mortality</strong></td>
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<td>Not estimable</td>
<td>459 (1 study)</td>
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<td>(stillbirth - death of fetus prior to birth; neonatal death - death within the first 28 days of birth; or infant death - death after the first 28 days)</td>
<td>See comment</td>
<td>See comment</td>
<td>459 (1 study)</td>
<td>⊕⊕⊕</td>
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<td><strong>Major neonatal morbidity</strong></td>
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<td>RR 0.15 (0.01 to 2.81)</td>
<td>459 (1 study)</td>
<td>⊕⊕⊕</td>
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<td>one or more of the following: hypoxic ischaemic encephalopathy (HIE) - grade II or III, necrotising enterocolitis (NEC), need for ongoing ventilation, meconium aspiration syndrome, seizures, need for therapeutic hypothermia Follow-up: 0-22 days</td>
<td>Study population</td>
<td></td>
<td>459 (1 study)</td>
<td>⊕⊕⊕</td>
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<td>Event</td>
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<td>RR</td>
<td>95% CI</td>
<td>Study No.</td>
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<td><strong>Neurodevelopmental disability/impairment</strong></td>
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<td>CBCL, Ages and Stages Questionnaire</td>
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<td>Follow-up: mean 2 years</td>
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<tr>
<td>13 per 1000</td>
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<td>2.04</td>
<td>(0.62 to 6.69)</td>
<td>459</td>
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<td>17 per 1000</td>
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<td>3.07</td>
<td>(0.13 to 74.87)</td>
<td>459</td>
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<td><strong>Maternal mortality</strong></td>
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<td>Follow-up: 0-10 days</td>
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<tr>
<td>0 per 1000</td>
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<td>0.92</td>
<td>(0.38 to 2.22)</td>
<td>459</td>
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<td><strong>Significant maternal morbidity</strong></td>
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<td>one or more of the following: significant postpartum haemorrhage requiring blood transfusion; maternal admission to intensive care unit; uterine rupture; hysterectomy</td>
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<td>43 per 1000</td>
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<td>0.88</td>
<td>(0.35 to 2.23)</td>
<td>545</td>
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<td><strong>Admission to NICU</strong></td>
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<td>33 per 1000</td>
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<td>1.02</td>
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<td>(100 to 245)</td>
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*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio;

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

---

1. There were no events for this outcome.
2. Few total events (<30).
3. Wide CI crossing line of no effect and RR > 25%.
4. Although all studies address outcome of NICU admission, 2 studies included additional outcome of intermediate nursery admission. Overall this may have compromised the total number of events comparatively.
5. One study did not give outcomes for elective C/S, only emergency C/S assessed.
6. Two out of three studies had wide CIs crossing the line of no effect.

CBCL: child behaviour checklist
NICU: neonatal intensive care unit
BACKGROUND

Fetal compromise can occur secondary to problems related to maternal, fetal or placental factors which result in inadequate oxygen or nutrient supply to the fetus. The presentation of fetal compromise in the term pregnancy is variable and can be suspected based on a number of factors. Intrauterine growth restriction (IUGR) and decreased fetal movement (DFM) are both indicative of either long-term or short-term placental insufficiency. Investigations routinely performed to assess fetal well-being, such as the cardiotocography (CTG) or ultrasound parameters such as amniotic fluid volume, fetal biometry and fetal/umbilical artery dopplers, can produce results leading to suspicion of a compromised fetus. Pathological results would necessitate the need for immediate delivery, but the management for 'suspicious' results remains unclear.

Description of the condition

The suspected compromised fetus in a term pregnancy can be identified by one of the following.

1. Clinical suspicion
   1. Maternal perception of decreased fetal activity is a common complaint, and one of the most frequent causes of unplanned visits in pregnancy. Between 4% and 15% of pregnant women will contact care providers with such concerns in the third trimester (Froen 2004). DFM has a well-established role as an adaptive response to the various stages of placental insufficiency and hypoxia (Froen 2008). Normal fetal movements (FM) are a highly specific indicator of fetal viability, and women presenting with DFM have a higher risk of stillbirth, fetal growth restriction, fetal distress, preterm birth and other associated outcomes (Froen 2008). Randomised trials however, have not shown that routine counting of fetal movements in low-risk pregnancies improves outcomes, and there is a lack of guidelines for the management of DFM as acknowledged in a recent Cochrane review (Hofmeyr 2012). The two guidelines currently available, from the Royal College of Obstetrics and Gynaecology in the UK and the Australia New Zealand Stillbirth Alliance, are based on consensus rather than strong evidence (ANZSA 2010; RCOG 2011).
   2. Fundal height measurement is a simple, inexpensive and widely used clinical screening test in assessing fetal growth and development in low-risk populations, despite the low detection rate with this method alone (Kean 1996).

2. Sonographic biometry/growth measurements

The accurate measurement and documentation of biometric parameters provide an important basis for the evaluation of fetal growth in the suspicion of growth disturbances such as IUGR and macrosomia (large baby).

1. IUGR is defined as failure of a baby to reach its growth potential. This can be due to maternal, fetal or placental factors and implies a pathological process distinct from defining a baby as small-for-gestational age (SGA). However, the distinction between IUGR and SGA tends to be blurred and in most cases IUGR identified in the antepartum period in fact refers to a SGA fetus with sonographically measured fetal dimensions, particularly abdominal circumference or estimated weight, below an age-specific threshold, typically the 10th percentile (Maulik 2004). True IUGR is considered one of the major complications of pregnancy. It increases the risk of perinatal mortality and morbidity, as well as long-term adverse consequences such as adult onset cardiovascular disease (Maulik 2006). Perinatal complications include prematurity, oligohydramnios (decreased amniotic fluid), non-reassuring fetal heart rate patterns with a higher incidence of caesarean delivery, birth asphyxia, low Appgar score, neonatal hypoglycaemia, hypocalcaemia, polycythaemia, hyperbilirubinaemia, hypothermia, apnoea, seizure disorders, and infection (Maulik 2004).
   2. Macrosomia describes a large fetus with an estimated fetal weight greater than the 90th percentile, or greater than 4500 g. This condition is also associated with increased fetal and neonatal morbidity and mortality. Outcomes looking at the effects of labour induction for suspected fetal macrosomia is the focus of another Cochrane review (Irion 1998), and will not be included in this review.

3. Doppler ultrasound

Doppler ultrasound provides a non-invasive method for the study of fetal haemodynamics and uses these findings for assessing the condition of the fetus. Doppler studies are valuable in high-risk women and generally, when performed earlier than 34 weeks’ gestation (Alfirevic 2013). The ability of this test to identify a compromised baby at term is less clear. When inadequate vascularisation of the placenta occurs (placental insufficiency), the following haemodynamic changes in the feto-placental circulation develop, often in a progressive fashion.
   1. Umbilical artery Doppler can detect increased resistance or absent or reversed end-diastolic flow. This reflects increasing placental vascular resistance.
   2. Fetal arterial Doppler (e.g. middle cerebral artery or aortic isthmus) can detect decreased resistance, indicative of protection of blood flow to the fetal brain in impaired placental function.
   3. Fetal venous Doppler (e.g. ductus venosus or inferior vena cava) can detect abnormalities which reflect preterminal impairment of cardiac function and fetal acidosis.

4. Cardiotocography (CTG)

Antenatal CTG is widely used as a screening test to indicate a normal condition of the fetus, with fetal heart rate response to movement being categorised as either reactive (normal) or non-
reactive (abnormal) (Everston 1979). Early studies indicated that a non-reactive antenatal CTG was associated with fetal acidosis and fetal demise (Brown 1981). However, a Cochrane review looking at antenatal CTG for fetal assessment showed no clear evidence that antenatal CTG improves perinatal outcomes (Grivell 2015), with the majority of studies being of low quality.

During the intrapartum period, a CTG may be described as normal, suspicious or pathological. Although clinical guidelines clearly recommend expediting delivery for a pathological CTG (NICE/RCOG 2007), management for the suspicious CTG is less prescriptive.

5. Biophysical profile (BPP)

Biophysical profile consists of CTG in combination with ultrasound to detect changes in fetal behaviour including fetal movement, tone and breathing, and amniotic fluid volume (deepest pool < 2 cm or > 2 cm), while monitoring the fetal heart rate. The combination of CTG and amniotic fluid volume assessment alone is called the modified biophysical profile.

6. Amniotic fluid volume

1. Oligohydramnios is defined in the term pregnancy as having an amniotic fluid index (AFI) of less than 5 cm or a single deepest vertical pocket measurement of less than 2 cm. It occurs in about 1% to 5% of pregnancies at term (Moore 1997). A number of studies over the past 15 years have shown an association between oligohydramnios and poor fetal outcomes. These were predominantly retrospective studies, which failed to control for the presence of factors known to be associated with oligohydramnios such as IUGR and urogenital malformations.

2. Polyhydramnios refers to excessive accumulation of amniotic fluid typically diagnosed when the AFI is greater than 20 cm or the single deepest vertical measures more than 8 cm. The incidence of polyhydramnios in a general obstetric population ranges from 0.2% to 1.6%. The relation between clinically obvious polyhydramnios and poor perinatal outcome has been well-documented. However, much less is known about mild, unexplained polyhydramnios, which usually is initially suggested by sonographic examination late in gestation. One study concluded that mild idiopathic polyhydramnios (defined as having an amniotic fluid index of 24.1 to 39.9) in late gestation is relatively common and except for a higher incidence of large-for-gestational age (LGA) fetuses, is not associated with an increased risk of adverse perinatal outcomes (Smith 1992).

How the intervention might work

If a baby is suspected to be compromised, earlier delivery may result in improved outcomes compared with expectant management where further compromise and/or emergency delivery may occur.

Description of the intervention

Determining the optimal timing of delivery in pregnancies with a suspected compromised fetus remains an issue even after 37 weeks’ gestation. The balance between allowing the fetus to remain in utero for the development of full lung maturation must be weighed against removing the fetus from an environment suspected to be harmful. Expectant management involves waiting more than 24 hours for spontaneous onset of labour in the absence of any other pregnancy complications or induction of labour for post-maturity greater than 41 weeks. Expectant management may result in complications associated with post-maturity such as perinatal mortality, meconium aspiration syndrome (Gülmezoglu 2012), hypoxic ischaemic encephalopathy and neonatal sepsis (Cheng 2008). Conversely, planned early birth may result in increased intervention and poor fetal outcomes (Seyb 1999). Planned early birth is planned delivery soon after presentation of a suspected compromised fetus. The mode of delivery may either be via induction of labour by any means and a vaginal delivery, or by caesarean section.

A Cochrane systematic review on induction of labour at term compared to expectant management demonstrated significant reductions in perinatal deaths and caesarean sections (Gülmezoglu 2012). Other studies found that the incidence of respiratory morbidity was halved for each week of prolongation of pregnancy between 37 and 39 + 6 weeks (Morrison 1995; Stutchfield 2005). The complications of planned early delivery may not be justified, especially in cases of misdiagnosis. A randomised controlled trial that compared preventive labour induction with expectant management for women with pre-specified risk factors actually showed a reduction in adverse outcomes such as caesarean section rate and neonatal intensive care unit (NICU) admission and an increase in uncomplicated vaginal deliveries (Nicholson 2008).

The decision to deliver the fetus immediately or wait either until labour commences or further signs merit delivery varies significantly among populations, institutions and practitioners within single institutions. In view of the high number of adverse outcomes associated with a suspected compromised fetus at term, there is a need to assess the benefits and harms of planned early delivery versus expectant management of women with a term pregnancy.

Why it is important to do this review

Fetal compromise in the term pregnancy is difficult to assess, however it is associated with significant adverse outcomes. Many cases...
have no obvious cause and management has to be aimed at determining the optimum time of delivery. Because there is inconsistency in clinical practice between centres and countries, a systematic review of the evidence for both early delivery and expectant management would be useful to guide clinical practice.

**OBJECTIVES**

To compare the fetal and maternal outcomes in expectant management versus planned early delivery for women presenting with a suspected compromised fetus from 37 weeks’ gestation or greater.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

Randomised or quasi-randomised controlled trials comparing expectant management versus planned early delivery for women with a suspected compromised fetus from 37 weeks’ gestation or more. In studies in which gestational ages overlapped more than 37 weeks’ gestation, we contacted researchers to provide further information.

Studies looking at immediate versus deferred delivery in pregnancies less than 36 weeks’ gestation in whom there is clinical suspicion of fetal compromise are the focus of another Cochrane review (Stock 2012).

We planned to consider studies published only as an abstract for inclusion and to add these to ‘Studies awaiting classification’ pending further information.

**Types of participants**

Pregnant women who are at 37 weeks’ gestation or more presenting with clinical suspicion of fetal compromise as defined by triallists. We planned to include women presenting with decreased fetal movement, abnormal ultrasound and/or biophysical profile (BPP) results, oligohydramnios or polyhydramnios, growth measurements consistent with fetal growth restriction, and non-reassuring CTG tracings. We excluded trials involving women with any other known medical disorders.

**Types of interventions**

Planned early birth versus expectant management.

Planned early birth is planned delivery soon after presentation of a suspected compromised fetus. Induction of labour should be initiated within 24 hours of randomisation. The mode of delivery may either be via induction of labour by any means and a vaginal delivery, or by caesarean section.

Expectant management involves waiting more than 24 hours for spontaneous onset of labour or, if immediate delivery becomes necessary, in the absence of any other pregnancy complications, or induction of labour for post-maturity greater than 41 weeks.

**Types of outcome measures**

**Primary outcomes**

Fetal, neonatal and infant

1. Perinatal mortality (stillbirth - death of fetus prior to birth; neonatal death - death within the first 28 days of birth; or infant death - death after the first 28 days).

2. Major neonatal morbidity (i.e. one or more of the following: hypoxic ischaemic encephalopathy (HIE) - grade II or III, necrotising enterocolitis (NEC), need for ongoing ventilation, meconium aspiration syndrome, seizures, need for therapeutic hypothermia).


Maternal and birth


2. Significant maternal morbidity (one or more of the following: significant postpartum haemorrhage requiring blood transfusion; maternal admission to intensive care unit; uterine rupture; hysterectomy).

**Secondary outcomes**

Fetal, neonatal and infant

1. Gestational age at birth.

2. Respiratory distress syndrome.

3. Apgar score less than seven at five minutes.

4. Resuscitation required.

5. Use of mechanical ventilation.

6. Days of mechanical ventilation.

7. Birthweight less than the 10th centile.

8. Meconium aspiration.


10. Admission to NICU.

11. Length of stay in NICU.

12. Interval between randomisation and delivery.

13. Sepsis as defined by administration of antibiotics for more than three days.

14. Moderate or severe hypoxic ischaemic encephalopathy (grade II or III).
15. Need for therapeutic hypothermia.

Not pre-specified
1. Gestational age ≥ 40 weeks.
2. Birthweight < 2.3 percentile.
3. Admission to intermediate care nursery.

Maternal and birth
1. Caesarean section
2. Placental abruption.
3. Pre-eclampsia.
4. Induction of labour.
5. Vaginal birth.
7. Days of antenatal hospitalisation.
8. Days of postnatal hospitalisation.
11. Postnatal depression.
12. Postnatal infection.

Not pre-specified
1. Maternal hospital stay.

Search methods for identification of studies
The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Electronic searches
We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register by contacting the Trials Search Co-ordinator (31 May 2015). The Cochrane Pregnancy and Childbirth Group’s Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:
1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.
Details of the search strategies for CENTRAL, MEDLINE, Embase and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the ‘Specialized Register’ section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources
We searched reference lists of published guidelines and other review articles. We contacted researchers to provide further information. We did not apply any language or date restrictions.

Data collection and analysis
The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Selection of studies
Two review authors independently assessed for inclusion all the potential studies identified as a result of the search strategy.

Data extraction and management
We designed a data extraction form based on the recommendations in the Cochrane Pregnancy and Childbirth Group. For eligible studies, two review authors independently extracted the data using the form (DB and AG). Discrepancies were resolved through discussion. Data were entered into Review Manager software (RevMan 2014) by one author (DB) and checked for accuracy by two others (BdV, AG).

For two studies we contacted the authors directly for additional information.

Assessment of risk of bias in included studies
Two review authors independently assessed risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

(1) Random sequence generation (checking for possible selection bias)
We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We assessed the method as:
• low risk of bias (any truly random process, e.g. random number table; computer random number generator);
• high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
• unclear risk of bias.
(2) Allocation concealment (checking for possible selection bias)
We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as:
- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)
We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:
- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)
We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes. We described methods used to blind outcome assessment as:
- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)
We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook. We assessed methods as:
- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; ‘as treated’ analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)
We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:
- low risk of bias (where it is clear that all of the study’s pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study’s pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)
We described for each included study any important concerns we had about other possible sources of bias. We assessed whether each study was free of other problems that could put it at risk of bias:
- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias
We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the Handbook (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Assessment of the quality of the evidence using the GRADE approach
We assessed the quality of the evidence using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes.

1. Perinatal mortality
2. Major neonatal morbidity
3. Neurodevelopmental disability/impairment (of infant)
4. Maternal mortality
5. Significant maternal morbidity
We used the GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

**Measures of treatment effect**

**Dichotomous data**

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

**Continuous data**

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. In future updates, we will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

**Unit of analysis issues**

**Cluster-randomised trials**

No cluster-randomised trials were identified by the search strategy. However, if such trials are identified in the future, provided that they are otherwise eligible, we will include them in updates of the review and will analyse them along with individually-randomised trials. We will report on whether the sample size was estimated based on the intra-cluster correlation co-efficient (ICC) using methods described in the Handbook and whether the trial had been analysed at the cluster level (the unit of randomisation) or at the level of the individual.

**Cross-over trials**

We considered cross-over trials inappropriate for this review question and were therefore not eligible for inclusion.

**Dealing with missing data**

For included studies, we noted levels of attrition. For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

**Assessment of heterogeneity**

We assessed statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics. We regarded heterogeneity as substantial if an I² was greater than 30% and either a Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. Had we identified substantial heterogeneity (above 30%), we planned to explore it by pre-specified subgroup analysis.

**Assessment of reporting biases**

In future updates of this review, if there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

**Data synthesis**

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials’ populations and methods were judged sufficiently similar. In future updates, if more studies are included in meta-analysis and clinical heterogeneity is apparent, sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average of the range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials. If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

**Subgroup analysis and investigation of heterogeneity**

In future updates, if we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses.
will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses.

1. Singleton and multiple pregnancies.
2. Term (37 to 40 + 6 weeks) and post-term (≥ 41 weeks) pregnancies.
3. Reason for suspected compromise, e.g. decreased fetal movement or suspected IUGR/SGA.

We will use the following outcomes in subgroup analysis.

1. Perinatal mortality.
2. Major neonatal morbidity.
5. Significant maternal morbidity.

We will assess subgroup differences by interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

In future updates, we will perform sensitivity analysis to explore the effect of trial quality on results, where there is risk of bias associated with the quality of some of the included trials. We will also use sensitivity analysis to explore the effects of fixed-effect or random-effects analysis for outcomes with statistical heterogeneity and the effects of any assumptions made.

We will use the following outcomes in sensitivity analysis.

1. Perinatal mortality.
2. Major neonatal morbidity.
5. Significant maternal morbidity.

RESULTS

Description of studies

Details of the studies are listed in the Characteristics of included studies table.

Results of the search

The search of the Cochrane Pregnancy and Childbirth Group retrieved 20 reports of seven studies. Of these, 12 reports were based on one study, three based on another and the remaining five reports on individual studies. Three studies met our criteria of comparing early delivery versus expectant management for the term compromised fetus. Four of the studies (six reports) were excluded. See Figure 1.
Figure 1. Study flow diagram.

20 records identified through database searching

20 records screened

20 full-text articles assessed for eligibility

6 full-text articles (4 studies) excluded, with reasons

3 studies (14 reports) included in qualitative synthesis

3 studies included in quantitative synthesis (meta-analysis)
Included studies

We identified two studies comparing early delivery with expectant management in the term fetus with intrauterine growth restriction (IUGR) and one study comparing early delivery with expectant management in the term fetus with suspected oligohydramnios. (See Characteristics of included studies.) These three studies included a total of 546 participants whose data contributed to this review. Two-hundred and sixty-nine women were in the early delivery group and 277 in the expectant management group.

van den Hove 2006 was a pilot randomised controlled trial (RCT) for the DIGIT AT trial conducted in The Netherlands between January 2002 and April 2004 that included pregnant women with suspected IUGR after 37 weeks’ gestation. Thirty-three women were randomised: 16 women were allocated to the labour induction group, and 17 to await the spontaneous onset of labour.

Boers 2010 was a multicentre randomised equivalence trial (DIGIT AT) conducted in The Netherlands between November 2004 and November 2008. The trial included pregnant women between 36 and 41 weeks’ gestation with suspected IUGR and who were under specialised obstetric care. Six-hundred and fifty women were randomised; 321 to induction of labour, and 329 to expectant management. For this review, data were extracted from 459 term infants ≥ 37 weeks’ gestation; 227 to induction of labour and 232 to expectant management.

The DIGIT AT trial generated 11 additional records: one protocol (Boers 2007), five abstracts (Boers 2009; Chauhan 2012; Tajik 2012; Van Wyk 2012; Willekes 2011), and five manuscripts (Bijlenga 2011; Boers 2012; Tajik 2014; Van Wyk 2012a; Vijgen 2013). Data from two substudies (Boers 2012; Van Wyk 2012a) contributed additional neonatal outcomes not included in the original paper.

Ek 2005 was a prospective pilot RCT conducted in Sweden from late 1999 until spring 2001. The trial included pregnant women referred at 41 completed weeks with uncomplicated pregnancies and an amniotic fluid index (AFI) < 50 mm. Fifty-four women were randomised: 26 to expectant management and 28 to induction of labour.

Excluded studies

Four studies comprising the six remaining reports were excluded from this review. (See Characteristics of excluded studies.)

Dogra 2012 randomised 50 pregnant women in India between 38 and 41 weeks with acquired and congenital heart disease into elective induction and spontaneous labour groups. Randomisation was not based on suspicion of fetal compromise as defined in this review and did not meet our inclusion criteria. The study results have not yet been published.

Conway 2000 was an abstract publication only with no final published manuscript. The study included pregnant women in the US between 37 and 41 weeks’ gestation with an AFI ≤ 5 cm. The limited data provided in the abstract were unable to be utilised without information on numbers randomised to each arm. The study author was contacted for this specific information; however, to date this has not been received.

Nicholson 2008 was an RCT conducted in the US that randomised pregnant women between 32 and 37.5 weeks’ gestation. Randomisation was based on pre-specified risk factors - demographic or medical and not on suspicion of fetal compromise as defined in this review. Nicholson 2007 was the published abstract for this study. Peek 2009 is a published letter to the journal regarding the IMOR IPAT study.

Pri-Paz 2008 was a prospective RCT entitled “Active Management Of Risk In Pregnancy At Term to Reduce Rate of Cesarean Deliveries (AMOR-IPAT)”. Its aim was to determine if active management of risks in pregnancy at term by inducing patients would not decrease the caesarean delivery rate or change neonatal outcomes. No published results were found for this trial, only a link stating the trial had been terminated. Multiple attempts to contact the author for results were unsuccessful.

Risk of bias in included studies

All included studies were RCTs. Summaries for the risk of bias of the included studies are given in Figure 2 and Figure 3. Overall, we judged the three trials to be at a low risk of bias.
Figure 2. ‘Risk of bias’ graph: review authors’ judgements about each risk of bias item presented as percentages across all included studies.

- Random sequence generation (selection bias)
- Allocation concealment (selection bias)
- Incomplete outcome data (attrition bias)
- Selective reporting (reporting bias)
- Other bias
- Blinding of participants and personnel (performance bias)
- Blinding of outcome assessment (detection bias)

Legend:
- Low risk of bias
- Unclear risk of bias
- High risk of bias

0% 25% 50% 75% 100%
Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.
Other potential sources of bias

Allocation

Random sequence generation
A low risk of bias was attributed to two of the studies. In the Boers 2010 study, women were randomly allocated to either induction or expectant monitoring in a 1:1 ratio using varied sized block randomisation with stratification for centre and parity. In the van den Hove 2006 pilot RCT, patients were randomly allocated by drawing of a sealed opaque envelope. Two series of envelopes, one for nulliparous and another for multiparous women, were filled at random by a statistician with a folded paper “induction” or “expectation” and numbered consecutively. The envelopes were opened in sequence of numbers in presence of the patient. No envelope was missed. Patients in the Ek 2005 trial were randomised, by sealed envelopes, after having given informed consent. It was unclear as to how the randomisation sequence was generated.

Allocation concealment
Although the Boers 2010 study entered all data into a secure web-based database, it is unclear whether a centralised telephone allocation service was used, therefore we considered the risk of bias unclear. It was not mentioned what kind of envelopes were used in the Ek 2005 study. We considered this to be an unclear risk of bias. van den Hove 2006 clearly specified that sealed opaque envelopes were used giving it a low risk of bias.

Blinding

Blinding of participants and personnel (performance bias)
In all three studies, the intervention was such that participants and personnel could not be blinded, however this is likely to be a low risk of bias secondary to the intervention being assessed.

Blinding of outcome assessment (detection bias)
In the Boers 2010 study, the outcome assessors were not blinded, however we have considered this as a low risk of bias secondary to the nature of the outcomes being collected, e.g. mortality is not subject to bias in reporting. Ek 2005 and van den Hove 2006 did not provide this information and were therefore considered unclear.

Incomplete outcome data
All three studies analysed their results with intention-to-treat and were therefore considered at low risk of bias.

Selective reporting
All the pre-specified outcomes were reported on in all three studies. In two of the trials, Boers 2010 and van den Hove 2006, some of the pre-specified outcomes were only reported on a subgroup of infants who were admitted to a neonatal or special care nursery due to the nature of the condition. Selective reporting was therefore considered to be a low risk of bias.

Other potential sources of bias
We did not identify any other potential sources of bias related to duplicate publication, location, citation, language, or outcome reporting bias.

Effects of interventions
See: Summary of findings for the main comparison Planned early delivery compared with expectant management for improving outcomes of the term suspected compromised baby

Planned early delivery versus expectant management
See Summary of findings for the main comparison

Primary outcomes

Fetal, neonatal and infant
Overall, there was no statistical difference between early delivery and expectant management in the neonatal primary outcomes. Boers 2010 (459 women) was the only study that reported outcomes associated with perinatal mortality (not estimable, evidence graded moderate, Analysis 1.1), and major neonatal morbidity (risk ratio (RR) 0.15, 95% confidence interval (CI) 0.01 to 2.81, evidence graded low, Analysis 1.2). Boers 2012 reported outcomes on neonatal seizures (not estimable, Analysis 1.6) and Van Wyk 2012a reported on the neurodevelopmental disability/impairment at two years of age: (RR 2.04, 95% CI 0.62 to 6.69, evidence graded low, Analysis 1.3). Both of these were based on the 2010 study of 459 women.
Maternal

There was also no statistical difference between the two randomisation arms in any of the primary maternal outcomes. Boers 2010 (459 women) was the only study that reported maternal mortality (RR 3.07, 95% CI 0.13 to 74.87, evidence graded low, Analysis 1.4), and major maternal morbidity (RR 0.92, 95% CI 0.38 to 2.22, evidence graded low, Analysis 1.5). One woman randomised to early delivery died at home 10 days after delivery. No cause for her death was found, there was no uterine rupture and it was classified as a serious unrelated adverse event (Boers 2010).

Secondary outcomes

Fetal, neonatal and infant

More infants in the early delivery group were admitted to the intermediate care nursery (Boers 2010; van den Hove 2006) (RR 1.28, 95% CI 1.02 to 1.61, Analysis 1.18). The total numbers included 491 infants; 243 in the early delivery group, and 248 in the expectant management group. There was no statistical difference in the risk of necrotising enterocolitis (one trial, 333 infants, Analysis 1.7), respiratory distress syndrome (one trial, 333 infants, Analysis 1.8), meconium aspiration (one trial, 459 infants, Analysis 1.9), Apgar score less than seven at five minutes (three trials, 546 infants, Analysis 1.12), resuscitation required (one trial, 459 infants, Analysis 1.13), mechanical ventilation (one trial, 337 infants, Analysis 1.14), admission to NICU (RR 0.88, 95% CI 0.35 to 2.23; three trials, 545 infants, evidence graded very low, Analysis 1.17), length of stay in NICU/SCN (one trial, 459 infants, Analysis 1.19), and sepsis (two trials, 366 infants, Analysis 1.21). The gestational age at birth in one trial of 459 participants was approximately 10 days less in those women randomised to early delivery (mean difference (MD) -9.50, 95% CI -10.82 to -8.18, Analysis 1.10) (Boers 2010), and women in the early delivery group were less likely to have a baby beyond 40 weeks’ gestation (RR 0.10, 95% CI 0.01 to 0.67, Analysis 1.11). The interval between randomisation and delivery in the same study was approximately nine days less in women randomised to early delivery (MD -8.68, 95% CI -10.04 to -7.32, Analysis 1.20) (Boers 2010). Although birthweight < 10th percentile was not significant between the two groups (RR 0.98, 95% CI 0.88 to 1.10; two trials, 491 infants, Analysis 1.15), both Boers 2010 and van den Hove 2006 reported birthweights stratified into groups of < 2.3rd percentile, 2.3rd - 5th percentile, and 5th to 10th percentile, based on the Dutch Kloosterman birthweight curves, which are standard stratifications for that country (Visser 2009). As a result, we performed a post hoc stratification of babies into the smallest of these three groups (two trials, 491 infants). Babies in the expectant management group were more likely to be < 2.3rd centile for birthweight (RR 0.51, 95% CI 0.36 to 0.73, Analysis 1.16).

No data were reported for the pre-specified secondary neonatal outcomes of the number of days of mechanical ventilation, moderate-severe hypoxic ischaemic encephalopathy or need for therapeutic hypothermia.

Maternal

Similarly, there was no statistical difference between early delivery versus expectant management in any of the maternal secondary outcomes that were reported on in the included studies; caesarean section rates (three trials, 546 women, evidence graded low, Analysis 1.22), placental abruption (one trial, 459 women, Analysis 1.23), pre-eclampsia (one trial, 459 women, Analysis 1.24), vaginal birth (three trials 546 women, Analysis 1.26), assisted vaginal birth (three trials 546 women, Analysis 1.27), breastfeeding rates (one trial, 218 women, Analysis 1.28) and number of weeks of breastfeeding after delivery (one trial, 124 women, Analysis 1.29). The increase in induction in the early delivery group in one trial of 459 women (RR 2.05, 95% CI 1.78 to 2.37, Analysis 1.25) (Boers 2010), is consistent with the intervention.

No data were reported for secondary maternal outcomes of postnatal infection, maternal satisfaction or views of care. Some data are reported for postnatal depression in the Bijlenga 2011 report of the Boers 2010 study, but data are not reported separately for women ≥ 37 weeks’ gestation. However, the published analysis showed no difference in the outcome of postnatal depression between the groups in the full cohort of women, which included those ≥ 36 weeks (574 women).

As we did not identify heterogeneity in the included studies, we did not carry out subgroup analysis. There were too few studies to carry out a sensitivity analysis.

DISCUSSION

Summary of main results

We identified three studies which examined whether early planned birth versus expectant management resulted in improved outcomes for the suspected compromised term baby: two studies examining babies with intrauterine growth restriction (IUGR) (van den Hove 2006, Boers 2010), and one trial examining babies with oligohydramnios (Ek 2005). These studies included a total of 546 participants (269 in the early delivery group and 277 in the expectant management group). Most of the pre-specified outcomes were reported by the largest of the three studies (Boers 2010). Overall, there was no statistical difference between the two groups in any of our pre-specified outcomes. However when stratifying the birthweights into smaller cohorts, infants in the expectant management group showed a significant increase in the proportion of babies whose weight was < 2.3rd percentile as compared
with infants in the early delivery group. This may suggest that these fetuses were severely growth restricted and did not continue to grow along their own expected growth curve as would a constitutionally small fetus (Boens 2010). In women randomised to planned early delivery, the gestational age at birth was on average 10 days earlier; women were less likely to have a baby beyond 40 weeks’ gestation, they were more likely to be induced and infants were more likely to be admitted to intermediate care nursery. The results are informed by only one large trial and two smaller trials assessing fetuses with IUGR or oligohydramnios and therefore cannot be generalised to all term pregnancies with suspected fetal compromise.

**Overall completeness and applicability of evidence**

The studies were underpowered to be able to detect a statistical difference in the primary outcome of perinatal mortality. Only one study of 459 women contributed significant data for this review. The smaller studies reported on considerably fewer outcomes. There was no significant heterogeneity seen for any of the reported outcomes.

We were unable to include one study found in our search as it was a published abstract only and did not include information on numbers randomised to each arm (Conway 2000). As a result we were unable to use the data included. The author has been contacted but has not yet supplied the requested information. We found no studies examining the effects of early delivery versus expectant management for the suspected compromised baby as indicated by decreased fetal movements, abnormal doppler ultrasound, suspicious cardiocotography (CTG) or polyhydramnios.

**Quality of the evidence**

All three trials were judged to be of generally low risk of bias. One trial (Ek 2005) did not mention how allocation concealment was preserved. All pre-specified outcomes were reported in the included studies.

The level of evidence was graded moderate (perinatal mortality), low (major neonatal morbidity, neurodevelopmental disability/impairment, maternal mortality, major maternal morbidity, caesarean section) or very low (admission to NICU) (Summary of Findings for the Main Comparison). The evidence was downgraded for imprecision for all outcomes, due to few events for all outcomes except caesarean section, and wide confidence intervals crossing the line of no effect for all outcomes except perinatal mortality. The evidence was also downgraded for indirectness for the outcomes admission to the neonatal intensive care unit (NICU) and caesarean section, due to differences in the recording of these outcomes in the included studies.

**Potential biases in the review process**

The evidence in this review is derived from studies identified in a detailed search process. With the exception of one trial with a published abstract only (Conway 2000), other trials comparing early delivery with expectant management of the term suspected compromised baby that have not been published may not have been identified.

**Agreements and disagreements with other studies or reviews**

We are not aware of any other systematic reviews on this topic. Studies within the review seemed to be in reasonable agreement.

**Authors’ Conclusions**

**Implications for practice**

Currently, there is insufficient evidence on the benefits and harms of planned early delivery versus expectant management for the suspected compromised fetus at or near term to inform clinical practice. Planned early delivery versus expectant management for a suspected compromised fetus at term did not demonstrate any differences in major outcomes of perinatal mortality, significant neonatal or maternal morbidity or neurodevelopmental disability. In women randomised to planned early delivery, the gestational age at birth was on average 10 days earlier; women were less likely to have a baby beyond 40 weeks’ gestation, they were more likely to be induced, and infants were more likely to be admitted to intermediate care nursery. There was a significant difference in the proportion of babies with a birthweight centile < 2.3 however this did not translate into reduction in morbidly. The review is informed by only one large trial and two smaller trials assessing fetuses with IUGR or oligohydramnios and therefore cannot be generalised to all term pregnancies with suspected fetal compromise.

**Implications for research**

There are other indications for suspecting compromise in a fetus at or near term, such as maternal perception of decreased fetal movements, ultrasound and/or CTG abnormalities and future research needs to assess effectiveness of optimal timing of delivery for these indications. Robust research is needed in the form of large, well-designed randomised trials that are powered to detect important outcomes such as mortality and severe morbidity.

**Acknowledgements**
As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group’s international panel of consumers and the Group’s Statistical Adviser.

This project was supported by the National Institute for Health Research, via Cochrane programme Grant funding to Cochrane Pregnancy and Childbirth. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

Helen West (HW) assisted with the production of the GRADE ‘Summary of findings’ table. HW is supported by the NIHR Cochrane Programme Grant Project: 13/89/05 - Pregnancy and childbirth systematic reviews to support clinical guidelines.

The authors would like to thank Kim Boers and Saskia le Cessie for provision of outcome data for those women randomised at 37 weeks or greater and Sverker Ek for responding to request for additional information.

References to studies included in this review

Boers 2010  [published data only]


Ek 2005  [published data only]

van den Hove 2006  [published data only]
References to studies excluded from this review

Conway 2000 [published data only]

Dogra 2012 [published data only]

Nicholson 2008 [published data only]


Pri-Paz 2008 [published data only]

Additional references

Alfirevic 2013

ANZSA 2010

Bijlenga 2011

Boers 2007

Boers 2009

Boers 2012

Boulvain 2001

Brown 1981

Chauhan 2012

Cheng 2008

Evertson 1979

Froen 2004

Froen 2008

Grivell 2015

Gülmezoglu 2012
Gülmezoglu AM, Crowther CA, Middleton P, Heatley E. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database

Higgins 2011

Hofmeyr 2012

Irion 1998

Kean 1996

Maulik 2004

Maulik 2006

Moore 1997

Morrison 1995

NICE/RCOG 2007

Nicholson 2007

Novikova 2011

Peek 2009

RCOG 2011

RevMan 2014

Seyb 1999

Smith 1992

Stock 2012

Stutchfield 2005

Tajik 2012

Tajik 2014

Van Wyk 2012
Van Wyk 2012a

Vijgen 2013

Visser 2009

Willekes 2011

* Indicates the major publication for the study
## CHARACTERISTICS OF STUDIES

### Characteristics of included studies  
*ordered by study ID*

#### Boers 2010

<table>
<thead>
<tr>
<th>Methods</th>
<th>Multicentre randomised equivalence trial.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td></td>
</tr>
</tbody>
</table>
**Setting:** 8 academic and 44 non-academic hospitals in The Netherlands between November 2004 and November 2008  
**Inclusion criteria:** pregnant women between 36 + 0 and 41 + 0 weeks’ gestation who had a singleton fetus in cephalic presentation, suspected intrauterine growth restriction and who were under specialised obstetric care. Suspected intrauterine growth restriction was defined as fetal abdominal circumference below the 10th percentile, estimated fetal weight below the 10th percentile, flattening of the growth curve in the third trimester (as judged by a clinician), or the presence of all 3 factors  
**Exclusion criteria:** exclusion criteria were previous caesarean section, diabetes mellitus or gestational diabetes requiring insulin therapy, renal failure, HIV seropositivity, prelabour rupture of membranes, severe pre-eclampsia, HELLP syndrome (haemolysis, elevated liver enzymes, and low platelet count), or a fetus with aneuploidy or congenital abnormalities suspected on ultrasound. Fetuses with decreased or absent movements, and those with abnormal heart rate tracings, were also excluded  
**Number randomised:** 650 women - 321 to induction of labour and 329 to expectant management in overall study, which included women from 36 weeks’ gestation. For this review data included term infants $\geq$ 37 weeks’ gestation - total 459 randomised - 227 to induction of labour and 232 to expectant management |
| **Interventions** |  
**Induction of labour group:** participants allocated to the induction of labour group were induced within 48 hours of randomisation. If the Bishop score at randomisation was greater than 6, labour was induced with amniotomy and, if necessary, augmented with oxytocin. Otherwise cervical ripening was performed with intracervical or intravaginal prostaglandin or a Foley balloon catheter  
**Expectant management:** women were monitored until the onset of spontaneous labour with daily fetal movement counts and twice-weekly heart rate tracings, ultrasound examination, maternal blood pressure measurement, assessment of proteinuria, laboratory tests of liver and kidney function, and full blood count. Induction of labour or planned caesarean section was performed for obstetrical indications |
| **Outcomes** |  
**Primary:** initial study: Composite measure of adverse neonatal outcome defined as death before hospital discharge, 5-minute Apgar score of less than 7, umbilical artery pH of less than 7.05, or admission to neonatal intensive care  
Follow-up study: 2-year neurodevelopmental outcomes using ages and stages questionnaire and the child behaviour checklist  
**Secondary:** caesarean section, instrumental vaginal delivery, length of stay in the neonatal intensive care or neonatal ward, length of stay in the maternal hospital, and maternal morbidity (defined as postpartum haemorrhage of more than 1000 mL, development of gestational hypertension or pre-eclampsia, eclampsia, pulmonary oedema, thromboembolism, or any other serious adverse event) |

---

Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review)  
Copyright © 2015 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Participant data were entered into a secure web-based database. Women were randomly allocated to either induction or expectant monitoring in a 1:1 ratio using varied sized block randomisation with stratification for centre and parity</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Secure web-based database - unclear whether centralised telephone allocation</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Complete outcome data reported and analysis by intention-to-treat</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported on.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No apparent risk of other bias.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Low risk</td>
<td>Participants and personnel not blinded, however, this is likely to be a low risk of bias secondary to the intervention being assessed</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Outcome assessors not blinded - In initial study, primary outcomes not subject to bias, e.g. mortality, weight, gestational age, however in the follow-up study there is potential for bias in the interpretation of the developmental measures used</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Ek 2005

**Methods**
- **Prospective pilot RCT.**

**Participants**
- **Setting:** Department of Obstetrics and Gynaecology, Karolinska University Hospital, Huddinge, Sweden from late 1999 until spring 2001
- **Inclusion criteria:** patients referred at 41 completed weeks with uncomplicated pregnancies; amniotic fluid index < 50 mm
- **Exclusion criteria:** estimated fetal size < -22%; pathological umbilical artery blood flow; abnormal cardiotocograph
- **Number randomised:** 54 women, 26 to expectant management and 28 to induction of labour
**Interventions**

**Induction of labour:** induction of labour was performed the same or following day. Patients with unfavourable cervix had a transcervical Foley catheter inserted for a maximum of 7 hours prior to amniotomy and oxytocin infusion, while patients with a favourable cervix primarily had amniotomy and oxytocin infusion.

**Expectant management:** no monitoring was done prior to spontaneous onset of labour. Those who did not go into labour spontaneously by 42 completed weeks were then managed according to department protocol.

**Outcomes**

**Primary maternal:** mode of delivery.

**Secondary maternal:** day at delivery.

**Primary fetal:** umbilical cord pH; Apgar score at 1, 5 and 10 minutes.

**Secondary fetal:** birthweight; number of admissions to the neonatal intensive care unit.

**Notes**

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Patients were randomised, by sealed envelopes, after having given informed consent. No mention is made of how the randomisation sequence was generated.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No mention is made as to how concealment was preserved. The information was stored in anonymous protocols at evaluation.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Trial was based on intention to treat. All patients completed the study and there were no treatment withdrawals.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All pre-specified outcomes reported on.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No apparent risk of other bias.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Low risk</td>
<td>This information was not provided however this is likely to be a low risk of bias secondary to the intervention being assessed.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>This information was not provided.</td>
</tr>
</tbody>
</table>
### Methods
Pilot RCT.

### Participants
**Setting:** Department of Obstetrics and Gynaecology, Atrium Medical Centre, Heerlen, The Netherlands between January 2002 and April 2004

**Inclusion criteria:** pregnant women with suspected intrauterine growth restriction after 37 weeks' gestation, based on clinical examination (measuring fundal height) and/or ultrasound biometry (fetal abdominal circumference (FAC) < 10th percentile or a declining FAC curve), singleton pregnancy; an accurate ultrasound dating scan performed before 20 weeks; a normal cardiocograph; and doubt by the attending clinician whether to induce or to await spontaneous delivery

**Exclusion criteria:** patients with multifetal pregnancies, uncertain gestational age, abnormal fetal presentations, or maternal diseases requiring induction of labour

**Number randomised:** 33 consented to take part. 16 were allocated to the labour induction group, and 17 to await spontaneous onset of labour

### Interventions
Patients were randomly allocated after stratification for parity to either induction of labour within 48 hours (labour induction group) or to await spontaneous onset of labour (expectant management group). Methods of labour induction were prostaglandin gel for cervical ripening and amniotomy and oxytocin intravenously according to local practice and individual preference. Participants allocated to the expectant management group were monitored with weekly measurement of the umbilical artery Doppler waveform and cardiocography twice weekly. Additional monitoring was done if indicated. Labour was induced in the expectant management group if the clinician considered this necessary on the basis of changes in foetal or maternal condition

### Outcomes
**Primary:** obstetrical intervention rates and neonatal outcomes.

### Notes

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Patients were randomly allocated by drawing of a sealed opaque envelope. 2 series of envelopes, 1 for nulliparous and another for multiparous women, were filled at random by a statistician with a folded paper “induction” or “expectation” and numbered consecutively. The envelopes were opened in sequence of numbers in presence of the patient. No envelope was missed</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Sealed opaque envelopes were used.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Analyses were performed by intention-to-treat. All patients completed the study and there were no treatment withdrawals</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>The primary outcomes were reported.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No apparent risk of other bias.</td>
</tr>
</tbody>
</table>
van den Hove 2006  (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conway 2000</td>
<td>Abstract publication only. Unable to use data without information on numbers randomised to each arm. The author has been contacted but has not yet supplied the requested information</td>
</tr>
<tr>
<td>Dogra 2012</td>
<td>This study randomised women with acquired and congenital heart disease and not suspicion of fetal compromise as defined in this review. Study results not yet published</td>
</tr>
<tr>
<td>Nicholson 2008</td>
<td>Randomised women 32 - 37.5 weeks. Randomised based on pre-specified risk factors - demographic or medical. Therefore, not randomised on suspicion of fetal compromise as defined in this review</td>
</tr>
<tr>
<td>Pri-Paz 2008</td>
<td>A prospective randomised controlled trial entitled &quot;Active Management Of Risk In Pregnancy At Term to Reduce Rate of Cesarean Deliveries (AMOR-IPAT)&quot;. It's aim was to determine if active management of risks in pregnancy at term by inducing patients would not decrease the caesarean delivery rate or change neonatal outcomes. No published results were found for this trial, only a link stating the trial had been terminated. Multiple attempts to contact the author for results were unsuccessful</td>
</tr>
</tbody>
</table>

RCT: randomised controlled trial

**Characteristics of excluded studies  [ordered by study ID]**

Blinding of participants and personnel (performance bias)
- Low risk
  - This information was not provided however this is likely to be a low risk of bias secondary to the intervention being assessed

Blinding of outcome assessment (detection bias)
- Unclear risk
  - This information was not provided.
## Comparison 1. Planned early delivery versus expectant management

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Perinatal mortality</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>2 Major neonatal morbidity</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.15 [0.01, 2.81]</td>
</tr>
<tr>
<td>3 Neurodevelopmental disability/impairment</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.04 [0.62, 6.69]</td>
</tr>
<tr>
<td>4 Maternal mortality</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.07 [0.13, 74.87]</td>
</tr>
<tr>
<td>5 Major maternal morbidity</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.92 [0.38, 2.22]</td>
</tr>
<tr>
<td>6 Neonatal seizures</td>
<td>1</td>
<td>336</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>7 Necrotising enterocolitis</td>
<td>1</td>
<td>333</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>8 Respiratory distress syndrome</td>
<td>1</td>
<td>333</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.33 [0.01, 7.98]</td>
</tr>
<tr>
<td>9 Meconium aspiration</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.34 [0.01, 8.32]</td>
</tr>
<tr>
<td>10 Gestational age at birth (days)</td>
<td>1</td>
<td>459</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-9.5 [-10.82, -8.18]</td>
</tr>
<tr>
<td>11 Gestational age ≥ 40 weeks (not pre-specified)</td>
<td>1</td>
<td>33</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.10 [0.01, 0.67]</td>
</tr>
<tr>
<td>12 Apgar score &lt; 7 at 5 minutes</td>
<td>3</td>
<td>546</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.56 [0.50, 13.04]</td>
</tr>
<tr>
<td>13 Resuscitation required</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.11 [0.01, 2.10]</td>
</tr>
<tr>
<td>14 Requirement for mechanical ventilation</td>
<td>1</td>
<td>337</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.20 [0.01, 4.11]</td>
</tr>
<tr>
<td>15 Birthweight &lt; 10 centile</td>
<td>2</td>
<td>491</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.98 [0.88, 1.10]</td>
</tr>
<tr>
<td>16 Birthweight &lt; 2.3 centile (not pre-specified)</td>
<td>2</td>
<td>491</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.51 [0.36, 0.73]</td>
</tr>
<tr>
<td>17 Admission to NICU</td>
<td>3</td>
<td>545</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.88 [0.35, 2.23]</td>
</tr>
<tr>
<td>18 Admission to intermediate care nursery (not pre-specified)</td>
<td>2</td>
<td>491</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.28 [1.02, 1.61]</td>
</tr>
<tr>
<td>19 Length of stay in NICU/SCN (days)</td>
<td>1</td>
<td>459</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>0.0 [-1.28, 1.28]</td>
</tr>
<tr>
<td>20 Interval (days) between randomisation and delivery</td>
<td>1</td>
<td>459</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-8.68 [-10.04, -7.32]</td>
</tr>
<tr>
<td>21 Neonatal sepsis</td>
<td>2</td>
<td>366</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.18 [0.14, 72.75]</td>
</tr>
<tr>
<td>22 Caesarean section</td>
<td>3</td>
<td>546</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.02 [0.65, 1.59]</td>
</tr>
<tr>
<td>23 Placental abruption</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.07 [0.13, 74.87]</td>
</tr>
<tr>
<td>24 Pre-eclampsia</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.63 [0.27, 1.49]</td>
</tr>
<tr>
<td>25 Induction of labour</td>
<td>1</td>
<td>459</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.05 [1.78, 2.37]</td>
</tr>
<tr>
<td>26 Vaginal birth</td>
<td>3</td>
<td>546</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.98 [0.90, 1.07]</td>
</tr>
<tr>
<td>27 Assisted vaginal birth</td>
<td>3</td>
<td>546</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.19 [0.69, 2.04]</td>
</tr>
<tr>
<td>28 Breastfeeding</td>
<td>1</td>
<td>218</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.09 [0.85, 1.40]</td>
</tr>
<tr>
<td>29 Breastfeeding (weeks)</td>
<td>1</td>
<td>124</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>1.74 [-3.37, 6.85]</td>
</tr>
<tr>
<td>30 Maternal hospital stay (days) (not pre-specified)</td>
<td>1</td>
<td>33</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>1.0 [0.68, 1.32]</td>
</tr>
</tbody>
</table>
### Analysis 1.1. Comparison 1 Planned early delivery versus expectant management, Outcome 1 Perinatal mortality.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: Planned early delivery versus expectant management

Outcome: Perinatal mortality

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental (n/N)</th>
<th>Control (n/N)</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/227</td>
<td>0/232</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 0 (Control)

Heterogeneity: not applicable

Test for overall effect: not applicable

Test for subgroup differences: Not applicable

Favours [early delivery] Favours [expectant]

### Analysis 1.2. Comparison 1 Planned early delivery versus expectant management, Outcome 2 Major neonatal morbidity.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: Planned early delivery versus expectant management

Outcome: Major neonatal morbidity

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental (n/N)</th>
<th>Control (n/N)</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/227</td>
<td>3/232</td>
<td>100.0 % 0.15 [0.01, 2.81]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td>100.0 % 0.15 [0.01, 2.81]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 3 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.28 (P = 0.20)

Test for subgroup differences: Not applicable

Favours [early delivery] Favours [expectant]
### Analysis 1.3. Comparison 1 Planned early delivery versus expectant management, Outcome 3 Neurodevelopmental disability/impairment.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 3 Neurodevelopmental disability/impairment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>8/227</td>
<td>4/232</td>
<td>100.0 %</td>
<td>2.04 [0.62, 6.69]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td><strong>100.0 %</strong></td>
<td><strong>2.04 [0.62, 6.69]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 8 (Experimental), 4 (Control)

- Heterogeneity: not applicable
- Test for overall effect: Z = 1.18 (P = 0.24)
- Test for subgroup differences: Not applicable

---

### Analysis 1.4. Comparison 1 Planned early delivery versus expectant management, Outcome 4 Maternal mortality.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 4 Maternal mortality

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>1/227</td>
<td>0/232</td>
<td>100.0 %</td>
<td>3.07 [0.13, 74.87]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td><strong>100.0 %</strong></td>
<td><strong>3.07 [0.13, 74.87]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 1 (Experimental), 0 (Control)

- Heterogeneity: not applicable
- Test for overall effect: Z = 0.69 (P = 0.49)
- Test for subgroup differences: Not applicable

---

Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review) 32

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### Analysis 1.5. Comparison 1 Planned early delivery versus expectant management, Outcome 5 Major maternal morbidity.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 5 Major maternal morbidity

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>9/227</td>
<td>10/232</td>
<td>0.92 [0.38, 2.22]</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td></td>
<td>100.0%</td>
<td><strong>0.92 [0.38, 2.22]</strong></td>
</tr>
</tbody>
</table>

Total events: 9 (Experimental), 10 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.19 (P = 0.85)

Test for subgroup differences: Not applicable

---

### Analysis 1.6. Comparison 1 Planned early delivery versus expectant management, Outcome 6 Neonatal seizures.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 6 Neonatal seizures

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/168</td>
<td>0/168</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>168</strong></td>
<td><strong>168</strong></td>
<td></td>
<td></td>
<td><strong>Not estimable</strong></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 0 (Control)

Heterogeneity: not applicable

Test for overall effect: not applicable

Test for subgroup differences: Not applicable
### Analysis 1.7. Comparison 1 Planned early delivery versus expectant management, Outcome 7 Necrotising enterocolitis.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 7 Necrotising enterocolitis

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>0/168</td>
<td>0/165</td>
<td>Not estimable</td>
<td></td>
<td>Not estimable</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>168</strong></td>
<td><strong>165</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.33 [ 0.01, 7.98 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 0 (Control)
Heterogeneity: not applicable
Test for overall effect: not applicable
Test for subgroup differences: Not applicable

### Analysis 1.8. Comparison 1 Planned early delivery versus expectant management, Outcome 8 Respiratory distress syndrome.

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 8 Respiratory distress syndrome

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>0/168</td>
<td>1/165</td>
<td>0.33 [ 0.01, 7.98 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>168</strong></td>
<td><strong>165</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.33 [ 0.01, 7.98 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 1 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.69 (P = 0.49)
Test for subgroup differences: Not applicable
Analysis 1.9. Comparison 1 Planned early delivery versus expectant management, Outcome 9 Meconium aspiration.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes.

Comparison: 1 Planned early delivery versus expectant management.

Outcome: 9 Meconium aspiration.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
<th>Weight %</th>
<th>Risk Ratio M-H,Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/227</td>
<td>1/232</td>
<td></td>
<td>100.0</td>
<td>0.34 [0.01, 8.32]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td>100.0</td>
<td>0.34 [0.01, 8.32]</td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 1 (Control).
Heterogeneity: not applicable.
Test for overall effect: Z = 0.66 (P = 0.51).
Test for subgroup differences: Not applicable.

Analysis 1.10. Comparison 1 Planned early delivery versus expectant management, Outcome 10 Gestational age at birth (days).

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes.

Comparison: 1 Planned early delivery versus expectant management.

Outcome: 10 Gestational age at birth (days).

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental N</th>
<th>Mean (SD)</th>
<th>Control N</th>
<th>Mean (SD)</th>
<th>Mean Difference IV,Fixed, 95% CI</th>
<th>Weight %</th>
<th>Mean Difference IV,Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>227</td>
<td>269.7 (6.7)</td>
<td>232</td>
<td>279.2 (7.7)</td>
<td>-9.50 [-10.82, -8.18]</td>
<td>100.0</td>
<td>-9.50 [-10.82, -8.18]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>227</td>
<td></td>
<td>232</td>
<td></td>
<td></td>
<td>100.0</td>
<td>-9.50 [-10.82, -8.18]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable.
Test for overall effect: Z = 14.11 (P < 0.00001).
Test for subgroup differences: Not applicable.
### Analysis 1.11. Comparison 1 Planned early delivery versus expectant management, Outcome 11

**Gestational age ≥ 40 weeks (not pre-specified).**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 11 Gestational age ≥ 40 weeks (not pre-specified)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight %</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>van den Hove 2006</td>
<td>1/16</td>
<td>11/17</td>
<td>100.0 %</td>
<td>0.10</td>
<td>[ 0.01, 0.67 ]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>16</td>
<td>17</td>
<td>100.0 %</td>
<td>0.10</td>
<td>[ 0.01, 0.67 ]</td>
</tr>
</tbody>
</table>

Total events: 1 (Experimental), 11 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 2.37 (P = 0.018)

Test for subgroup differences: Not applicable

### Analysis 1.12. Comparison 1 Planned early delivery versus expectant management, Outcome 12

**Apgar score < 7 at 5 minutes.**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** 1 Planned early delivery versus expectant management

**Outcome:** 12 Apgar score < 7 at 5 minutes

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight %</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>5/227</td>
<td>2/232</td>
<td>100.0 %</td>
<td>2.56</td>
<td>[ 0.50, 13.04 ]</td>
</tr>
<tr>
<td>Ek 2005</td>
<td>0/28</td>
<td>0/26</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>0/16</td>
<td>0/17</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>271</td>
<td>275</td>
<td>100.0 %</td>
<td>2.56</td>
<td>[ 0.50, 13.04 ]</td>
</tr>
</tbody>
</table>

Total events: 5 (Experimental), 2 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.13 (P = 0.26)

Test for subgroup differences: Not applicable
### Analysis 1.13. Comparison 1 Planned early delivery versus expectant management, Outcome 13

**Resuscitation required.**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** Planned early delivery versus expectant management

**Outcome:** Resuscitation required

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/227</td>
<td>4/232</td>
<td>100.0%</td>
<td></td>
<td>0.11 [0.01, 2.10]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>227</td>
<td>232</td>
<td></td>
<td>100.0%</td>
<td>0.11 [0.01, 2.10]</td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 4 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 1.46 (P = 0.14)
Test for subgroup differences: Not applicable

---

Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review)
### Analysis 1.14. Comparison 1 Planned early delivery versus expectant management, Outcome 14

**Requirement for mechanical ventilation.**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** Planned early delivery versus expectant management

**Outcome:** Requirement for mechanical ventilation

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>0/169</td>
<td>2/168</td>
<td></td>
<td>100.0 %</td>
<td>0.20 [0.01, 4.11]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>169</strong></td>
<td><strong>168</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.20 [0.01, 4.11]</strong></td>
</tr>
</tbody>
</table>

Total events: 0 (Experimental), 2 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.05 (P = 0.30)

Test for subgroup differences: Not applicable

### Analysis 1.15. Comparison 1 Planned early delivery versus expectant management, Outcome 15

**Birthweight < 10 centile.**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** Planned early delivery versus expectant management

**Outcome:** Birthweight < 10 centile

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>159/227</td>
<td>165/231</td>
<td></td>
<td>92.8 %</td>
<td>0.98 [0.87, 1.10]</td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>12/16</td>
<td>13/17</td>
<td></td>
<td>7.2 %</td>
<td>0.98 [0.67, 1.44]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>243</strong></td>
<td><strong>248</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.98 [0.88, 1.10]</strong></td>
</tr>
</tbody>
</table>

Total events: 171 (Experimental), 178 (Control)

Heterogeneity: Chi² = 0.00, df = 1 (P = 1.00); I² = 0.0%

Test for overall effect: Z = 0.34 (P = 0.73)

Test for subgroup differences: Not applicable

---

Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes (Review)  
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## Analysis 1.16. Comparison 1 Planned early delivery versus expectant management, Outcome 16
Birthweight < 2.3 centile (not pre-specified).

### Review:
Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

### Comparison:
1 Planned early delivery versus expectant management

### Outcome:
16 Birthweight < 2.3 centile (not pre-specified)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>33/227</td>
<td>69/231</td>
<td>93.4% 0.49 [0.34, 0.71]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>4/16</td>
<td>5/17</td>
<td>6.6% 0.85 [0.28, 2.61]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>243</strong></td>
<td><strong>248</strong></td>
<td><strong>100.0% 0.51 [0.36, 0.73]</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 37 (Experimental), 74 (Control)
Heterogeneity: $\chi^2 = 0.85$, df = 1 ($P = 0.36$); $I^2 = 0.0%$
Test for overall effect: $Z = 3.73$ ($P = 0.00019$)
Test for subgroup differences: Not applicable
Analysis 1.17. Comparison 1 Planned early delivery versus expectant management, Outcome 17 Admission to NICU.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 17 Admission to NICU

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight %</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>6/227</td>
<td>6/231</td>
<td>1.02 [0.33, 3.11]</td>
<td>65.7</td>
<td></td>
</tr>
<tr>
<td>Ek 2005</td>
<td>2/28</td>
<td>3/26</td>
<td>0.62 [0.11, 3.41]</td>
<td>34.3</td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>0/16</td>
<td>0/17</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>271</strong></td>
<td><strong>274</strong></td>
<td></td>
<td><strong>100.0</strong></td>
<td><strong>0.88 [0.35, 2.23]</strong></td>
</tr>
</tbody>
</table>

Total events: 8 (Experimental), 9 (Control)
Heterogeneity: Chi² = 0.23, df = 1 (P = 0.63); I² = 0.0%
Test for overall effect: Z = 0.27 (P = 0.79)
Test for subgroup differences: Not applicable
**Analysis 1.18. Comparison 1 Planned early delivery versus expectant management, Outcome 18 Admission to intermediate care nursery (not pre-specified).**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** Planned early delivery versus expectant management

**Outcome:** Admission to intermediate care nursery (not pre-specified)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>93/227</td>
<td>74/231</td>
<td>89.4 % 1.28 [ 1.00, 1.63 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>11/16</td>
<td>9/17</td>
<td>10.6 % 1.30 [ 0.74, 2.27 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>243</strong></td>
<td><strong>248</strong></td>
<td><strong>100.0 %</strong> 1.28 [ 1.02, 1.61 ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 104 (Experimental), 83 (Control)

Heterogeneity: Chi$^2$ = 0.00, df = 1 (P = 0.96); I$^2$ =0.0%

Test for overall effect: Z = 2.15 (P = 0.032)

Test for subgroup differences: Not applicable

---

**Analysis 1.19. Comparison 1 Planned early delivery versus expectant management, Outcome 19 Length of stay in NICU/SCN (days).**

**Review:** Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

**Comparison:** Planned early delivery versus expectant management

**Outcome:** Length of stay in NICU/SCN (days)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV,Fixed,95% CI</td>
<td></td>
<td>IV,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>227 5.12 (5.38)</td>
<td>232 5.12 (8.37)</td>
<td>100.0 % 0.0 [ -1.28, 1.28 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td><strong>100.0 %</strong> 0.0 [ -1.28, 1.28 ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P = 1.0)

Test for subgroup differences: Not applicable
Analysis 1.20. Comparison 1 Planned early delivery versus expectant management, Outcome 20 Interval (days) between randomisation and delivery.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 20 Interval (days) between randomisation and delivery

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>227</td>
<td>232</td>
<td>-8.68 [-10.04, -7.32]</td>
<td>100.0 %</td>
<td>-8.68 [-10.04, -7.32]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>227</td>
<td>232</td>
<td>-8.68 [-10.04, -7.32]</td>
<td>100.0 %</td>
<td>-8.68 [-10.04, -7.32]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 12.51 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 1.21. Comparison 1 Planned early delivery versus expectant management, Outcome 21 Neonatal sepsis.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 21 Neonatal sepsis

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>0/168</td>
<td>0/165</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>1/16</td>
<td>0/17</td>
<td>3.18 [0.14, 72.75]</td>
<td>100.0 %</td>
<td>3.18 [0.14, 72.75]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>184</td>
<td>182</td>
<td>3.18 [0.14, 72.75]</td>
<td>100.0 %</td>
<td>3.18 [0.14, 72.75]</td>
</tr>
</tbody>
</table>

Total events: 1 (Experimental), 0 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.72 (P = 0.47)

Test for subgroup differences: Not applicable
### Analysis 1.22. Comparison 1 Planned early delivery versus expectant management, Outcome 22 Caesarean section.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: Planned early delivery versus expectant management

Outcome: 22 Caesarean section

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>30/227</td>
<td>26/232</td>
<td>76.2 % 1.18 [0.72, 1.93]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ek 2005</td>
<td>1/28</td>
<td>4/26</td>
<td>12.3 % 0.23 [0.03, 1.94]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>3/16</td>
<td>4/17</td>
<td>11.5 % 0.80 [0.21, 3.02]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>271</strong></td>
<td><strong>275</strong></td>
<td><strong>100.0 %</strong> 1.02 [0.65, 1.59]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 34 (Experimental), 34 (Control)

Heterogeneity: Chi$^2$ = 2.33, df = 2 (P = 0.31); I$^2$ = 14%

Test for overall effect: Z = 0.08 (P = 0.93)

Test for subgroup differences: Not applicable

### Analysis 1.23. Comparison 1 Planned early delivery versus expectant management, Outcome 23 Placental abruption.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: Planned early delivery versus expectant management

Outcome: 23 Placental abruption

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>1/227</td>
<td>0/232</td>
<td>100.0 % 3.07 [0.13, 74.87]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td><strong>100.0 %</strong> 3.07 [0.13, 74.87]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 1 (Experimental), 0 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.69 (P = 0.49)

Test for subgroup differences: Not applicable
### Analysis 1.24. Comparison 1 Planned early delivery versus expectant management, Outcome 24 Pre-eclampsia.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 24 Pre-eclampsia

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>8/227</td>
<td>13/232</td>
<td></td>
<td>100.0%</td>
<td>0.63 [0.27, 1.49]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>227</td>
<td>232</td>
<td></td>
<td>100.0%</td>
<td>0.63 [0.27, 1.49]</td>
</tr>
</tbody>
</table>

Total events: 8 (Experimental), 13 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.05 (P = 0.29)

Test for subgroup differences: Not applicable
Analysis 1.25. Comparison 1 Planned early delivery versus expectant management, Outcome 25 Induction of labour.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 25 Induction of labour

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>215/227</td>
<td>107/232</td>
<td>*</td>
<td>100.0%</td>
<td>2.05 [1.78, 2.37]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>227</strong></td>
<td><strong>232</strong></td>
<td>*</td>
<td>100.0%</td>
<td>2.05 [1.78, 2.37]</td>
</tr>
</tbody>
</table>

Total events: 215 (Experimental), 107 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 9.90 (P < 0.00001)
Test for subgroup differences: Not applicable


Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 26 Vaginal birth

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>177/227</td>
<td>186/232</td>
<td>*</td>
<td>84.7%</td>
<td>0.97 [0.89, 1.07]</td>
</tr>
<tr>
<td>Ek 2005</td>
<td>22/28</td>
<td>20/26</td>
<td></td>
<td>9.5%</td>
<td>1.02 [0.77, 1.36]</td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>12/16</td>
<td>13/17</td>
<td></td>
<td>5.8%</td>
<td>0.98 [0.67, 1.44]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>271</strong></td>
<td><strong>275</strong></td>
<td>*</td>
<td>100.0%</td>
<td>0.98 [0.90, 1.07]</td>
</tr>
</tbody>
</table>

Total events: 211 (Experimental), 219 (Control)
Heterogeneity: Chi² = 0.10, df = 2 (P = 0.95); I² = 0.0%
Test for overall effect: Z = 0.51 (P = 0.61)
Test for subgroup differences: Not applicable
Analysis 1.27.  Comparison 1 Planned early delivery versus expectant management, Outcome 27 Assisted vaginal birth.

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 27 Assisted vaginal birth

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H Fixed 95% CI</td>
<td></td>
<td>M-H Fixed 95% CI</td>
</tr>
<tr>
<td>Boers 2010</td>
<td>20/227</td>
<td>20/232</td>
<td>88.5 %</td>
<td>1.02 [ 0.57, 1.85 ]</td>
<td></td>
</tr>
<tr>
<td>Ek 2005</td>
<td>5/28</td>
<td>2/26</td>
<td>9.3 %</td>
<td>2.32 [ 0.49, 10.94 ]</td>
<td></td>
</tr>
<tr>
<td>van den Hove 2006</td>
<td>1/16</td>
<td>0/17</td>
<td>2.2 %</td>
<td>3.18 [ 0.14, 72.75 ]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>271</strong></td>
<td><strong>275</strong></td>
<td><strong>100.0 %</strong></td>
<td><strong>1.19 [ 0.69, 2.04 ]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 26 (Experimental), 22 (Control)
Heterogeneity: Chi² = 1.34, df = 2 (P = 0.51); I² = 0.0%
Test for overall effect: Z = 0.63 (P = 0.53)
Test for subgroup differences: Not applicable
**Analysis 1.28. Comparison 1 Planned early delivery versus expectant management, Outcome 28 Breastfeeding.**

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 28 Breastfeeding

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio (M-H,Fixed,95% CI)</th>
<th>Weight (%)</th>
<th>Risk Ratio (M-H,Fixed,95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>67/118</td>
<td>52/100</td>
<td>1.09 [0.85, 1.40]</td>
<td>100.0</td>
<td>1.09 [0.85, 1.40]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>118</strong></td>
<td><strong>100</strong></td>
<td></td>
<td><strong>100.0</strong></td>
<td><strong>1.09 [0.85, 1.40]</strong></td>
</tr>
</tbody>
</table>

Total events: 67 (Experimental), 52 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.70 (P = 0.48)

Test for subgroup differences: Not applicable

---

**Analysis 1.29. Comparison 1 Planned early delivery versus expectant management, Outcome 29 Breastfeeding (weeks).**

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes

Comparison: 1 Planned early delivery versus expectant management

Outcome: 29 Breastfeeding (weeks)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference (IV,Fixed,95% CI)</th>
<th>Weight (%)</th>
<th>Mean Difference (IV,Fixed,95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boers 2010</td>
<td>69 (17.38 (15.19))</td>
<td>55 (15.64 (13.8))</td>
<td>1.74 [-3.37, 6.85]</td>
<td>100.0</td>
<td>1.74 [-3.37, 6.85]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>69</strong></td>
<td><strong>55</strong></td>
<td></td>
<td><strong>100.0</strong></td>
<td><strong>1.74 [-3.37, 6.85]</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.67 (P = 0.50)

Test for subgroup differences: Not applicable
Analysis 1.30. Comparison 1 Planned early delivery versus expectant management, Outcome 30 Maternal hospital stay (days) (not pre-specified).

Review: Planned early delivery versus expectant management of the term suspected compromised baby for improving outcomes.

Comparison: 1 Planned early delivery versus expectant management.

Outcome: 30 Maternal hospital stay (days) (not pre-specified).

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>van den Hove 2006</td>
<td>16 4 (0.42)</td>
<td>17 3 (0.52)</td>
<td>1.00 % [ 0.68, 1.32 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>17</td>
<td>100.0 % 1.00 [ 0.68, 1.32 ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 6.09 (P < 0.00001)

Test for subgroup differences: Not applicable

CONTRIBUTIONS OF AUTHORS

Diana Bond is guarantor for the review. Diana Bond and Dr Adrienne Gordon were responsible for the design, co-ordination, research and writing of the review. All authors contributed with a clinical and methodological perspective as well as providing general advice for the review.

DECLARATIONS OF INTEREST

Diana Bond: We are grateful to the Stillbirth Foundation Australia for their generous funding to support the Sydney Stillbirth Study. SFA has had no input or influence regarding the publication of this review.

Angela Carberry: None known.

Adrienne Gordon: Diana bond is supported for her work on another project by a grant from the stillbirth foundation Australia. The charity was not involved with this review and we do not believe there is a conflict of interest.

Jon Hyett: None known.

Jonathan Morris: None known.

Bradley de Vries: I am employed by Royal Prince Alfred Hospital as a staff specialist obstetrician.
SOURCES OF SUPPORT

Internal sources
- No sources of support supplied

External sources
- Stillbirth Foundation, Australia.
- National Institute for Health Research (NIHR), UKNIHR Cochrane Programme Grant Project: 13/89/05 - Pregnancy and childbirth systematic reviews to support clinical guidelines, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This review includes additional outcomes not pre-specified in the protocol in order to include outcomes specified in the included studies. The additional outcomes are as follows.

1. Gestational age $\geq$ 40 weeks
2. Birthweight < 2.3 percentile (we have indicated in the review that we did a post hoc analysis of birthweight < 2.3 percentile and the reason why)
3. Admission to intermediate care nursery
4. Maternal hospital stay

This review also changed two maternal secondary outcomes.

1. Combined elective and emergency caesarean sections into one combined outcome
2. Deleted 'mode of induction' as this referred to induced women only, so was not a randomised comparison

The methods have been updated to include the current standard methods of Cochrane Pregnancy and Childbirth, including methods for GRADE and the incorporation of a 'Summary of findings' table. The background has been edited.

We have added information relating to Types of participants to specify that we will include women presenting with oligohydramnios or polyhydramnios, and growth measurements consistent with fetal growth restriction.