

Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing (Review)

Devane D, Lalor JG, Daly S, McGuire W, Smith V



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[Intervention Review]

Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Declan Devane¹, Joan G Lalor², Sean Daly³, William McGuire⁴, Valerie Smith²

¹School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland. ²School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland. ³Coombe Women & Infants University Hospital, Dublin 8, Ireland. ⁴Centre for Reviews and Dissemination, Hull York Medical School, University of York, York, UK

Contact address: Declan Devane, School of Nursing and Midwifery, National University of Ireland Galway, University Road, Galway, Ireland. declan.devane@nuigalway.ie.

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ABSTRACT

Background

The admission cardiotocograph (CTG) is a commonly used screening test consisting of a short (usually 20 minutes) recording of the fetal heart rate (FHR) and uterine activity performed on the mother's admission to the labour ward.

Objectives

To compare the effects of admission CTG with intermittent auscultation of the FHR on maternal and infant outcomes for pregnant women without risk factors on their admission to the labour ward.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (17 May 2011) (CENTRAL) (*The Cochrane Library* 2011 Issue 2 of 4), MEDLINE (1966 to 17 May 2011), CINAHL (1982 to 17 May 2011), Dissertation Abstracts (1980 to 17 May 2011) and the reference list of retrieved papers.

Selection criteria

All randomised and quasi-randomised trials comparing admission CTG with intermittent auscultation of the FHR for pregnant women between 37 and 42 completed weeks of pregnancy and considered to be at low risk of intrapartum fetal hypoxia and of developing complications during labour.

Data collection and analysis

Two authors independently assessed trial eligibility and quality, and extracted data. Data were checked for accuracy.

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Main results

We included four trials involving more than 13,000 women. All four studies included women in labour. Overall, the studies were at low risk of bias. Although not statistically significant using a strict $P < 0.05$ criterion, data are consistent with women allocated to admission CTG having, on average, a higher probability of an increase in incidence of caesarean section than women allocated to intermittent auscultation (risk ratio (RR) 1.20, 95% confidence interval (CI) 1.00 to 1.44, four trials, 11,338 women, $T^2 = 0.00$, $I^2 = 0\%$). There was no significant difference in the average treatment effect across included trials between women allocated to admission CTG and women allocated to intermittent auscultation in instrumental vaginal birth (RR 1.10, 95% CI 0.95 to 1.27, four trials, 11,338 women, $T^2 = 0.01$, $I^2 = 38\%$) and fetal and neonatal deaths (RR 1.01, 95% CI 0.30 to 3.47, four trials, 11339 infants, $T^2 = 0.00$, $I^2 = 0\%$).

Women allocated to admission CTG had, on average, significantly higher rates of continuous electronic fetal monitoring during labour (RR 1.30, 95% CI 1.14 to 1.48, three trials, 10,753 women, $T^2 = 0.01$, $I^2 = 79\%$) and fetal blood sampling (RR 1.28, 95% CI 1.13 to 1.45, three trials, 10,757 women, $T^2 = 0.00$, $I^2 = 0\%$) than women allocated to intermittent auscultation. There were no differences between groups in other secondary outcome measures.

Authors' conclusions

Contrary to continued use in some clinical areas, we found no evidence of benefit for the use of the admission cardiotocograph (CTG) for low-risk women on admission in labour.

We found no evidence of benefit for the use of the admission CTG for low-risk women on admission in labour. Furthermore, the probability is that admission CTG increases the caesarean section rate by approximately 20%. The data lacked power to detect possible important differences in perinatal mortality. However, it is unlikely that any trial, or meta-analysis, will be adequately powered to detect such differences. The findings of this review support recommendations that the admission CTG not be used for women who are low risk on admission in labour. Women should be informed that admission CTG is likely associated with an increase in the incidence of caesarean section without evidence of benefit.

PLAIN LANGUAGE SUMMARY

Comparing electronic monitoring of the baby's heartbeat on a woman's admission in labour using cardiotocography (CTG) with intermittent monitoring

Monitoring of the fetal heart rate (FHR) is one of the most common methods for checking a baby's wellbeing. The two most common ways of monitoring the FHR are by listening to the heart beat using a fetal stethoscope, Pinard (special trumpet shaped device), handheld Doppler ultrasound device (this is known as intermittent auscultation) or by an electronic fetal monitoring (EFM) machine that produces a paper printout of the baby's heart rate and the mother's contractions, called a cardiotocograph (CTG). The admission CTG is a commonly used test consisting of a short, usually 20 minute, recording of the FHR and uterine activity that is performed when the mother is admitted to the labour ward with signs of labour. The admission CTG was introduced to try and identify those babies who were at greatest risk of becoming compromised with a lack of oxygen during labour. These babies could be monitored more intensively by continuous electronic fetal monitoring, or they may benefit from an immediate intervention such as being delivered by caesarean section.

This review compared the admission CTG with intermittent auscultation of the FHR performed on the mother's admission to the labour ward. We included four randomised controlled trials involving more than 13,000 women with low-risk pregnancies in the review. Women allocated to admission CTG were more likely to have a caesarean section than women allocated to intermittent auscultation. There was no difference in the number of instrumental vaginal births or in the number of babies who died during or shortly after labour between women allocated to admission CTG and women allocated to intermittent auscultation. Admission CTG was associated with a significant increase in the use of continuous electronic fetal monitoring (with an electrode placed on the baby's scalp) and fetal blood sampling (a small blood sample taken from a baby's scalp) during labour. There were no differences in other outcomes measured such as artificial rupture of the membranes, augmentation of labour or use of an epidural.

BACKGROUND

Assessment of fetal wellbeing throughout pregnancy, labour and birth is widely regarded as a fundamental component of maternity care and essential for optimising fetal outcomes. Although a variety of methods are used to assess fetal well-being, including fetal movement counting and biophysical tests such as Doppler ultrasound, monitoring of the fetal heart rate (FHR) remains the most common method for the assessment of fetal wellbeing.

The FHR undergoes constant changes in response to changes in the intrauterine environment and to other stimuli such as uterine contractions. These changes in the FHR can be monitored to assess the wellbeing of the fetus during pregnancy and labour.

Description of the condition

The two most common methods of monitoring the FHR are by intermittent auscultation and by an electronic fetal monitoring (EFM) machine that produces a paper printout called a cardiotocograph (CTG). Intermittent auscultation involves listening to the fetal heart at predetermined intervals using either a Pinard stethoscope or a hand-held Doppler ultrasound device. The CTG is a graphical printout of the FHR and uterine contractions. The FHR recorded on a CTG may be recorded externally via an ultrasound transducer attached to the mother's abdomen, or internally via a fetal scalp electrode placed directly on the baby's head. Uterine contractions are recorded via a pressure transducer attached to the mother's abdomen or, less commonly, by an intrauterine pressure device placed in the uterine cavity.

Description of the intervention

The admission CTG is a commonly used screening test consisting of a short, usually 20 minute, recording of the FHR and uterine activity performed on the mother's admission to the labour ward with signs of labour. Currently, some women will have an admission CTG performed prior to assessments aimed at diagnosing the onset of labour, while others will not have the admission CTG until a diagnosis of labour has been established. The implications of this are that some women will have an admission CTG performed on admission to the labour ward or labour assessment room where, on subsequent assessment, a diagnosis of not being in labour is made. Differences in timing of the admission CTG with respect to the onset of labour may result in differences in outcomes assessed. We planned to explore this through subgroup analysis (*see 'Subgroup analysis and investigation of heterogeneity'*).

How the intervention might work

Pioneered in the 1950s and 1960s as an alternative to intermittent auscultation of the FHR by stethoscope or Pinard

(Caldeyro-Barcia 1966; Hammacher 1968; Hon 1958), EFM was introduced into widespread clinical practice in the 1970s to 1980s on the premise that it would facilitate early detection of abnormal FHR patterns thought to be associated with hypoxia (lack of oxygen), thus allowing earlier intervention to prevent fetal neurological damage and/or death (Nelson 1996).

However, because antenatal risk factors do not identify all fetuses who will subsequently experience morbidity and/or mortality, the admission CTG was introduced as a means of attempting to identify those fetuses of low-risk mothers at greatest risk of intrapartum hypoxia (Arulkumaran 2000; RCOG 2001) who might benefit from more intensive monitoring by continuous EFM and/or fetal scalp blood gas analysis or from immediate intervention (e.g. expedited birth).

Current prevalence rates of perinatal mortality, neonatal encephalopathy and cerebral palsy are relatively low and, of those, only a small proportion are thought to be attributable directly to intrapartum causes (RCOG 2001). Changes in FHR patterns are neither sensitive (the ability of a test to identify those who have the disease/condition) nor specific (the ability of the test to correctly identify those without the disease/condition) to any particular cause (MacLennan 1999). Multiple late decelerations and decreased FHR variability have been shown to be associated with an increased risk of cerebral palsy (Nelson 1996). However, the associated false positive rate is reported as high as 99.8% in the presence of tracings displaying these abnormalities in the FHR pattern (Nelson 1996). This poor positive predictive value implies that to identify the fetus who may be compromised, EFM identifies abnormal FHR patterns in many healthy fetuses who are not truly compromised.

Why it is important to do this review

There is a lack of evidence of benefit supporting the use of the admission CTG in low-risk pregnancy. Despite recommendations that it should not be recommended for this group of women (Liston 2007; NCCWCH 2007; RCOG 2001), the admission CTG was used by approximately 79% of maternity units in the UK in 2000 (CESDI 2001), by 96% of units in Ireland in 2004 (Devane 2007) and by approximately 76% of Canadian hospitals (Kaczorowski 1998). More recently, the admission CTG was used in all (100%, n = 42) labour units in Sweden in 2008 (Holzmann 2010).

Although the admission CTG remains in widespread use, several issues remain controversial. These include whether the admission CTG (a) should be offered routinely to all women without risk factors for intrapartum hypoxia; (b) whether the admission CTG is effective at predicting those fetuses who will subsequently develop intrapartum hypoxia; and (c) the effect of the admission CTG on neonatal mortality and on maternal and neonatal morbidity.

It is important to undertake this systematic review to explore these issues and to evaluate the efficacy of admission CTG compared to

intermittent auscultation as a method of assessing fetal wellbeing in women on admission to the labour ward, or labour assessment room, with signs of possible labour. This review compliments other Cochrane systematic reviews evaluating the effectiveness of other interventions for the assessment of fetal wellbeing including the following.

- Antenatal cardiotocography for fetal assessment (Grivell 2010)
- Regimens of fetal surveillance for impaired fetal growth (Grivell 2009)
- Fetal and umbilical Doppler ultrasound in high-risk pregnancies (Alfirevic 2010)
- Utero-placental Doppler ultrasound for improving pregnancy outcome (Stampalija 2010)
- Biochemical tests for placental function (Neilson 2003)
- Fetal movement counting for assessment of fetal wellbeing (Mangesi 2007)
- Fetal manipulation for facilitating tests of fetal wellbeing (Tan 2001a)
- Fetal vibroacoustic stimulation for facilitating tests of fetal wellbeing (Tan 2001b)
- Maternal glucose administration for facilitating tests of fetal wellbeing (Tan 2001c)
- Maternal glucose administration for facilitating test (East 2005)
- Amniotic fluid index versus single deepest vertical pocket as a screening test for predicting adverse pregnancy outcomes (Nabhan 2008)
- Biophysical profile for fetal assessment in high-risk pregnancies (Lalor 2008)

OBJECTIVES

To compare the effects of admission cardiotocograph with intermittent auscultation of the FHR on maternal and infant outcomes for pregnant women without risk factors for intrapartum hypoxia on their admission to the labour ward.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and quasi randomised trials comparing admission cardiotocograph (CTG) with intermittent auscultation of the FHR.

Types of participants

Pregnant women between 37 and 42 completed weeks of pregnancy and considered to be at low risk of intrapartum fetal hypoxia and of developing complications during labour. It is recognised that there is much debate surrounding the definition of what constitutes 'normality' and concerns have been expressed at what some regard as the disempowering concept of risk classification (Gail-Thomas 2003). In addition, the predictive value of risk scoring during pregnancy is poor (WHO 1999). However, given the consensus of opinion that continuous electronic fetal monitoring should be reserved for women whose fetuses are at high or increased risk of cerebral palsy, neonatal encephalopathy or perinatal death (Liston 2007; NCCWCH 2007; RANZCOG 2002; RCOG 2001), we will, where sufficient detail is provided by trial authors, determine eligibility of participants based on absence of risk factors identified in international guidelines for electronic fetal monitoring (see [Characteristics of included studies](#)).

Types of interventions

Admission CTG compared with intermittent auscultation of the FHR on admission to the labour ward.

For the purpose of this review we have used the following operational definitions.

- Admission CTG is defined as a commonly used screening test consisting of a short, usually 20 minute, recording of the FHR and uterine activity performed on the mother's admission to the labour ward.
- Intermittent auscultation is defined as intermittent surveillance of the FHR at predetermined intervals, using either a Pinard stethoscope or a hand-held Doppler, performed on the mother's admission to the labour ward.

Types of outcome measures

Primary outcomes

Maternal

1. Incidence of caesarean section.
2. Incidence of operative vaginal delivery.

Infant

1. Perinatal mortality rate (fetal and neonatal deaths excluding lethal congenital anomalies).
2. Severe neurodevelopmental disability assessed at greater than, or equal to, 12 months of age. We have defined severe neurodevelopmental disability as any one or a combination of the following: non-ambulant cerebral palsy, developmental delay (developmental quotient less than 70), auditory and visual impairment. Development should have been assessed by means

of a previously validated tool, such as Bayley Scales of Infant Development (Psychomotor Developmental Index and Mental Developmental Index (Bayley 1993)).

Secondary outcomes

Maternal

1. Incidence of serious maternal complications (e.g. admission to intensive care unit, septicaemia (a form of blood infection), organ failure).
2. Incidence of continuous electronic fetal monitoring during labour.
3. Incidence of artificial rupture of membranes during labour.
4. Incidence of oxytocin augmentation of labour.
5. Mobility during labour.
6. Perceived control and/or self-confidence during labour.
7. Incidence of use of pharmacological analgesia including regional analgesia.
8. Incidence of use of non-pharmacological methods of coping with labour and birth, e.g. transcutaneous electrical nerve stimulation, hydrotherapy.
9. Satisfaction with labour experience.
10. Incidence of fetal blood sampling.
11. Length of hospital stay.

Infant

1. Cardio-respiratory and/or neurological depression at birth as demonstrated by an Apgar score less than seven for longer than five minutes, or evidence of acidaemia indicated by a pH less than 7.0 or base deficit greater than 12 mmol/L in umbilical arterial cord blood, or neonatal blood sample within the first hour of life, or both.
2. Incidence and severity of hypoxic ischaemic encephalopathy. Severity of hypoxic ischaemic encephalopathy assessed using Sarnat staging (Sarnat 1976):
 - i) (a) stage 1 (mild): hyperalertness, hyper-reflexia, dilated pupils, tachycardia, absence of seizures;
 - ii) (b) stage 2 (moderate): lethargy, hyper-reflexia, miosis, bradycardia, seizures, hypotonia with weak suck and Moro reflexes;
 - iii) (c) stage 3 (severe): stupor, flaccidity, small to midposition pupils which react poorly to light, decreased stretch reflexes, hypothermia and absent Moro reflex.
3. Incidence of seizures in the neonatal period, either apparent clinically or detected by electro-encephalographic recordings.
4. Evidence of multi-organ compromise within the first 24 hours after birth: for example, renal failure, hepatic injury, cardiac damage, respiratory complications, or haematological insult.
5. Incidence of admission to neonatal special care and/or intensive care unit.

6. Length of stay to neonatal special care and/or neonatal intensive care unit.

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (17 May 2011).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
 2. weekly searches of MEDLINE;
 3. weekly searches of EMBASE;
 4. handsearches of 30 journals and the proceedings of major conferences;
 5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.
- Details of the search strategies for CENTRAL, MEDLINE and EMBASE, 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.

In addition, we searched CENTRAL (*The Cochrane Library* 2011, Issue 2 of 4), MEDLINE (1966 to 17 May 2011), CINAHL (1982 to 17 May 2011) and Dissertation Abstracts (1980 to 17 May 2011) using the search strategies detailed in [Appendix 1](#).

Searching other resources

We searched the reference list of papers identified through the above search strategy and assessed their suitability for inclusion in the review.

We did not apply any language restrictions.

Data collection and analysis

The methodology for data collection and analysis is based on the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins 2011).

Selection of studies

Two review authors (Declan Devane (DD) and Joan G Lalor (JGL)) assessed independently for inclusion all the potential studies identified as a result of the search strategy. We did not encounter any disagreement and therefore did not need to consult a third review author (Sean Daly (SD), William McGuire (WM) or Valerie Smith (VS)).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors (DD and JGL) extracted data using the data extraction form. We resolved any discrepancies through discussion and did not need to consult a third review author. Two review authors (DD and JGL) entered all data into the Review Manager (RevMan) software (RevMan 2011) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors (DD and VS) assessed the risk of bias for each study independently using The Cochrane Collaboration's tool for assessing risk of bias as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and contained in RevMan (RevMan 2011).

(1) 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 risk of bias for sequence generation:

- low risk (any truly random process, e.g. random number table; computer random number generator);
- high risk (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear risk.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation sequence and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the risk of bias for allocation concealment

- low risk (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk.

(3) Blinding (checking for possible performance bias)

It is likely not possible to blind participants or personnel in these trials. Given the differences in equipment required, it is usually apparent to both women and clinicians to which group a woman has been randomised (i.e. admission cardiotocograph or intermittent auscultation with Pinard or hand-held Doppler device). However, it would be possible to blind outcome assessors. Therefore, we assessed the risk of bias for blinding for outcome assessors as:

- high risk;
- low risk;
- unclear risk.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

For each included study, and for each outcome or class of outcomes, we describe completeness of data including attrition and exclusions from the analysis. We noted whether attrition and exclusions were reported, 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 was supplied by the trial authors, we re-included missing data in the analyses we undertook. We assessed the risk of bias for completeness of data as:

- low risk (20% or less missing data);
- high risk (more than 20% missing data);
- unclear risk.

(5) Selective reporting bias

We investigated the possibility of selective outcome reporting bias by identifying all outcomes reported in the methods section of the results publication and cross-checking to see if these were reported in the results section of the trial publication(s).

We assessed the risk of bias for selective reporting as:

- high risk (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 failed to include results of a key outcome that would have been expected to have been reported);
- low risk (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- unclear risk.

(6) Other sources of bias

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. We judged the risk of bias as:

- low risk;
- high risk;
- unclear risk.

(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 as likely to have impacted on the findings.

We assessed the overall risk of bias for each included study as:

- low risk;
- high risk;
- unclear risk.

Measures of treatment effect

Dichotomous data

For dichotomous data, we present results as summary risk ratios with 95% confidence intervals.

Continuous data

For continuous data, we used the mean difference where outcomes were measured in the same way between trials.

Unit of analysis issues

Cluster-randomised trials

We did not find any cluster-randomised trials from our search. In future updates, if we identify cluster-randomised trials we will include them in the analyses along with individually randomised trials. We will adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using [Sensitivity analysis](#). 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 of women randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We regarded heterogeneity as substantial where T^2 was greater than zero and either I^2 was greater than 30% or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In future updates, 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, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by [Egger 1997](#), and for dichotomous outcomes we will use the test proposed by [Harbord 2006](#). If we detect asymmetry in any of these tests or by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analyses using the Review Manager software ([RevMan 2011](#)). The largest of the four included trials ([Impey 2003](#)) included women in whom the liquor was known to be clear (i.e. only women who had either a spontaneous rupture of the membranes or an amniotomy were included in the study). This knowledge of the presence of clear liquor would have given clinicians an additional clinical feature used in the assessment of fetal well being that would not have been available for all women included in the other three trials ([Cheyne 2003](#); [Mires 2001](#); [Mitchell 2008](#)) where membrane rupture and clear liquor were not inclusion criteria. Because of this, we believed that there was clinical heterogeneity sufficient to expect that the underlying treatment effects would differ between the included trials (and in particular between the [Impey 2003](#) trial and the other three trials ([Cheyne 2003](#); [Mires 2001](#); [Mitchell 2008](#))). We therefore used random-effects meta-analysis to produce an overall summary of the average treatment effect across the four included trials. We have treated this random-effects summary as the average range of possible treatment effects. For each outcome reported, we present

the results of the random-effects analyses as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analysis using *a priori* outcomes.

1. Women in-labour versus women not in-labour on clinical assessment post admission cardiotocograph.

However, all four studies included only women in labour (at point of intervention) and therefore this subgroup analysis was not possible. We will perform this subgroup analysis in future updates if data are available. For fixed-effect inverse variance meta-analyses we will assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we will assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

We had planned to perform a sensitivity analysis based on trial quality, separating high-quality trials from trials of lower quality. 'High quality' was, for the purposes of this sensitivity analysis, defined as a trial having 'low risk of bias' for allocation concealment and a reasonable loss to follow-up (less than 20% of outcome data). However, we assessed all four included studies as having low risk of bias in random sequence generation and allocation concealment and none had more than 20% outcome data missing for outcomes included in this review. Therefore, the planned sensitivity analysis was not required but may be carried out in future updates if data permit.

We investigated substantial statistical heterogeneity (*see Assessment of heterogeneity*) using sensitivity analyses.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of ongoing studies](#).

Results of the search

The search of the Cochrane Pregnancy and Childbirth Group's Trials Register found seven reports and our search of the other databases did not identify any additional reports. These seven reports related to four completed ([Cheyne 2003](#); [Impey 2003](#); [Mires 2001](#); [Mitchell 2008](#)) and one ongoing study ([Devane 2008](#)).

Included studies

We included four studies with 13,296 women ([Cheyne 2003](#); [Impey 2003](#); [Mires 2001](#); [Mitchell 2008](#)) (*see Characteristics of included studies*). We did not exclude any study and found one ongoing study ([Devane 2008](#), *see Characteristics of ongoing studies*). The studies were conducted in Scotland ([Cheyne 2003](#); [Mires 2001](#)), Ireland ([Impey 2003](#)) and England ([Mitchell 2008](#)), and ranged in number of participants from 334 women ([Cheyne 2003](#)) to 8628 women ([Impey 2003](#)). The four included studies included women in labour. Therefore, we were unable to perform our planned subgroup analysis by whether or not women were in labour or not on clinical assessment post the admission cardiotocograph (CTG) (*see Subgroup analysis and investigation of heterogeneity*).

Three studies included women in spontaneous labour only ([Cheyne 2003](#); [Mitchell 2008](#); [Mires 2001](#)) and one included women who were in spontaneous or induced labour ([Impey 2003](#)). All studies included women who were regarded as being at 'low risk' of maternal and fetal complications with the exception of [Impey 2003](#) who included a relatively small (approximately 5%) proportion of women with a previous caesarean section and prior to 37 completed weeks' gestation. Details on participant inclusion criteria, including what constituted 'low risk' are given in [Characteristics of included studies](#).

Women allocated to admission CTG received a routine 15-minute ([Mitchell 2008](#)) or 20-minute ([Cheyne 2003](#); [Impey 2003](#); [Mires 2001](#)) tracing. Women allocated to intermittent auscultation received intermittent auscultation of the fetal heart for at least one full minute ([Cheyne 2003](#); [Impey 2003](#); [Mires 2001](#); [Mitchell 2008](#)) during and after a contraction ([Cheyne 2003](#); [Mires 2001](#)) or after a contraction only ([Impey 2003](#); [Mitchell 2008](#)).

Excluded studies

We did not exclude any studies.

Risk of bias in included studies

We assessed the risk of bias in included studies within the domains of (i) random sequence generation (selection bias) (ii) allocation concealment (selection bias) (iii) blinding of outcome assessment (detection bias) (iv) incomplete outcome data (attrition bias) (v) selective reporting (reporting bias) (vi) other bias and (vi) overall risk of bias (*see Assessment of risk of bias in included studies* above). Overall, the studies were at low risk of bias across most domains with some exceptions, which are detailed below.

Allocation

We assessed all four included studies as having low risk of bias in random sequence generation and in allocation concealment.

Blinding

We felt it unreasonable to expect blinding of participants and professionals providing care (*see Assessment of risk of bias in included studies*). Risk of bias for blinding for outcome assessors was assessed as low for two studies (Impey 2003; Mires 2001), unclear for one (Mitchell 2008) and high risk in one where outcome assessment was not blinded (Cheyne 2003).

Incomplete outcome data

Overall, loss to follow-up was low across all outcomes for all four studies with the exception of umbilical cord blood gas analyses (arterial pH, venous pH and base deficit/base excess (BD/BE)). Two studies included this outcome (Impey 2003; Mires 2001) but the range of values used for this outcome in both these studies differed from that prespecified in this review and therefore we have not used these data. For information, Impey 2003 reports missing data for the outcome 'pH less than seven or BD/E greater than 12 mmol/L' of 7.5% and 7.8% for ACTG and IA respectively. Mires 2001 reports missing data for their primary outcome of metabolic acidosis defined as 'pH less than 7.20 or BD greater than 8 mmol/L' of 26% and 27% for ACTG and IA respectively. One study reported a loss to follow-up of 7% (n = 22) of women (Cheyne 2003). However, data were identified and extracted subsequently for 21 of these 22 women by the trial author and kindly provided to the review team.

Selective reporting

All four studies reported all outcomes mentioned in the methods section in the results section of the trial publication(s) and were therefore assessed as being at low risk of selective reporting.

Other potential sources of bias

We identified no other sources of potential bias in three of the four studies (Cheyne 2003; Impey 2003; Mitchell 2008). One study (Mires 2001) recruited women (n = 3752) to the study and randomised them to admission CTG or intermittent auscultation during the third trimester. However, some women developed an obstetric complication between randomisation and admission in labour that warranted continuous FHR monitoring in labour, such that only 2367 women were judged to be low risk when in labour (1186 admission CTG, 1181 intermittent auscultation). Of the 1885 women randomised to intermittent auscultation in the third trimester, 704 (37%) developed complications during pregnancy and required admission CTG on admission. This is addressed further under [Sensitivity analysis](#).

Effects of interventions

Admission cardiotocography versus intermittent auscultation (low-risk women, four studies, 11339 women)

For this comparison, we have included all women as randomised in the Cheyne 2003 and Mitchell 2008 studies and the subgroups of low-risk women in the Impey 2003; Mires 2001 studies (*see Characteristics of included studies* and *Sensitivity analysis* for details).

Primary outcomes

The difference in the average treatment effect across included trials between women allocated to admission CTG and women allocated to intermittent auscultation in caesarean section has a risk ratio (RR) of 1.20 and a 95% confidence interval (CI) of 1.00 to 1.44, four trials, 11,338 women, [Analysis 1.1](#)). Given that (i) the 95% CI just reaches 1.00 and (ii) the absence of measurable heterogeneity in this outcome analysis ($T^2 = 0.00$, $I^2 = 0\%$), the probability is that admission CTG increases the caesarean section rate by approximately 20%. There was no significant difference in the average treatment effect across included trials between women allocated to admission CTG and women allocated to intermittent auscultation in instrumental vaginal birth (RR 1.10, 95% CI 0.95 to 1.27, four trials, 11,338 women, $T^2 = 0.01$, $I^2 = 38\%$, [Analysis 1.2](#)) and fetal and neonatal deaths (RR 1.01, 95% CI 0.30 to 3.47, four trials, 11,339 infants, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 1.8](#)). None of the included studies reported data for the outcome 'Severe neurodevelopmental disability assessed at greater than, or equal to, 12 months of age'.

Secondary outcomes

Women allocated to admission CTG had, on average, significantly higher rates of continuous electronic fetal monitoring during labour (RR 1.30, 95% CI 1.14 to 1.48, three trials, 10,753 women, $T^2 = 0.01$, $I^2 = 79\%$, [Analysis 1.3](#)) and fetal blood sampling (RR 1.28, 95% CI 1.13 to 1.45, three trials, 10,757 women, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 1.7](#)) than women allocated to intermittent auscultation.

There was no significant difference in the average treatment effect across included trials between women allocated to admission CTG and women allocated to intermittent auscultation in amniotomy (RR 1.04, 95% CI 0.97 to 1.12, two trials, 2,694 women, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 1.4](#)), oxytocin for augmentation of labour (RR 1.05, 95% CI 0.95 to 1.17, four trials, 11,324 women, $T^2 = 0.00$, $I^2 = 34\%$, [Analysis 1.5](#)), epidural (RR 1.11, 95% CI 0.87 to 1.41, three trials, 10,757 women, $T^2 = 0.03$, $I^2 = 86\%$, [Analysis 1.6](#)), Apgar score less than seven at or after five minutes (RR 1.00, 95% CI 0.54 to 1.85, four trials, 11,324 infants, $T^2 = 0.10$, $I^2 = 25\%$, [Analysis 1.11](#)), hypoxic ischaemic encephalopathy (RR 1.19, 95% CI 0.37 to 3.90, one trial, 2,367 infants, heterogeneity not applicable, [Analysis 1.12](#)), admission to neonatal intensive care units (RR 1.03, 95% CI 0.86 to 1.24, four trials, 11,331

infants, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 1.10](#)), neonatal seizures (RR 0.72, 95% CI 0.32 to 1.61, one trial, 8056 infants, heterogeneity not applicable, [Analysis 1.13](#)), evidence of fetal multi-organ compromise within the first 24 hours after birth (RR 0.56, 95% CI 0.19 to 1.67, one trial, 8056 infants, heterogeneity not applicable, [Analysis 1.9](#)), length of stay in neonatal intensive care (hours) (mean difference (MD) 6.20 hours, 95% CI -8.70 to 21.10, one trial, 318 infants, heterogeneity not applicable, [Analysis 1.15](#)) and length of stay in neonatal intensive care (days) (MD 1.80, 95% CI -0.59 to 4.19, one trial, 91 infants, heterogeneity not applicable, [Analysis 1.14](#)).

Data were not reported, were unavailable or were unavailable in a format that could be used in this review for the following secondary outcomes.

Maternal

1. Incidence of serious maternal complications (e.g. admission to intensive care unit, septicaemia (a form of blood infection), organ failure).
2. Mobility during labour.
3. Perceived control and/or self-confidence during labour.
4. Incidence of use of non pharmacological methods of coping with labour, e.g. transcutaneous electrical nerve stimulation, hydrotherapy.
5. Satisfaction with labour experience.
6. Length of hospital stay.

Sensitivity analyses

One study ([Mires 2001](#)) recruited women ($n = 3752$) to the study and randomised them to admission CTG or intermittent auscultation during the third trimester. However, some women developed an obstetric complication between randomisation and admission in labour that warranted continuous FHR monitoring in labour, such that only 2367 women were judged to be at low risk when in labour (1186 admission CTG, 1181 intermittent auscultation). Of the 1885 women randomised to intermittent auscultation in the third trimester, 704 (37%) developed complications during pregnancy and required an admission CTG on admission to the labour ward. However, the proportion of women who developed complications were similar in each group, suggesting an absence of differential treatment of women post-randomisation. The trial author kindly provided data separately for the outcomes in this subgroup of women, and we have included these data in the main analyses in this review (see [Characteristics of included studies](#)). A second study ([Impey 2003](#)) randomised women at the point of labour. However, this study included a relatively small number (less than 5%) of women who had a previous lower segment caesarean section and who went into labour prior to 37 completed weeks' gestation. The trial author kindly provided data separately for the outcomes for women (i) between 37 and 42 completed weeks with (ii) no previous caesarean section and we have included these data

in the main analyses in this review. We explored the dependency of the findings of this review on the decision to use data from the low-risk subgroups of women in both the [Impey 2003](#) and [Mires 2001](#) studies through a post-hoc sensitivity analysis in which the primary analysis was repeated with data from the whole groups as randomised in both studies. Results for this were consistent with primary comparison effects for the low-risk subgroup of women with the exception of two outcomes. Caesarean section became statistically significant, with significantly more women allocated to admission CTG having, on average, a caesarean section compared with women allocated to intermittent auscultation (RR 1.17, 95% CI 1.02 to 1.34, four trials, 13247 women, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 2.1](#)). Epidural also became significant, with significantly more women allocated to intermittent auscultation having, on average, an epidural compared with women allocated to admission CTG (RR 1.11, 95% CI 1.01 to 1.22, two trials, 4085 women, $T^2 = 0.00$, $I^2 = 0\%$, [Analysis 2.6](#)).

In the primary comparison, three outcomes (instrumental vaginal birth, continuous electronic fetal monitoring during labour and epidurals) had significant statistical heterogeneity where T^2 was greater than zero and either I^2 was greater than 30% or there was a low P value (less than 0.10) in the χ^2 test for heterogeneity. On investigating this heterogeneity, we found that the [Mires 2001](#) study appeared to drive the heterogeneity for instrumental vaginal birth and continuous electronic fetal monitoring during labour. When [Mires 2001](#) was removed from each of these two outcomes, the heterogeneity was no longer substantial. Removal of [Mires 2001](#) for each of these two outcomes did not alter the direction or significance of the effect. Heterogeneity for the third outcome, epidural, seemed to be driven by [Impey 2003](#), which in contrast to the direction of effect of the other two studies included in this outcome, found a non-significant reduction in epidurals in women allocated to admission CTG.

DISCUSSION

This review includes four trials ([Cheyne 2003](#); [Impey 2003](#); [Mires 2001](#); [Mitchell 2008](#)) involving more than 13,000 women. All four studies included women in labour.

The admission cardiotocograph (CTG) was introduced as a means of attempting to identify those fetuses at greatest risk of intrapartum hypoxia ([Arulkumaran 2000](#); [RCOG 2001](#)) who might benefit from more intensive monitoring by continuous electronic fetal monitoring and/or fetal scalp blood gas analysis or from immediate intervention (e.g. expedited birth). Although there was no significant difference, using a strict $P = 0.05$ criterion, in caesarean sections, on average, between women allocated to admission CTG and women allocated to intermittent auscultation, the probability is that admission CTG increases the caesarean section rate by approximately 20%. This is reinforced by the 95% CI just reach-

ing 1.00 and by the absence of measurable heterogeneity in this outcome analysis. Further, all four included studies found fewer caesarean sections associated with intermittent auscultation, although no individual study showed a statistically significant difference. Although numbers needed to treat/harm (NNT/H) analyses remain controversial in the context of meta-analysis and should be interpreted with caution, we estimate that, overall, one additional caesarean section was performed for every 136 women monitored continuously (95% CI 69 to 5641, risk difference (controls-treated) = -0.0074 (-0.015 to -0.0002)).

Women allocated to admission CTG had a significantly higher rate, on average, of continuous electronic fetal monitoring during labour and fetal blood sampling than women allocated to intermittent auscultation.

All four included studies provide relevant evidence on the effects of the admission CTG compared with intermittent auscultation on maternal and infant outcomes for pregnant women without risk factors on their admission to the labour ward. There are three important points in discussing how the results of the review fit into the context of current practice. Firstly, the largest study in this review (Impey 2003) included women in which the colour of the liquor was known to be clear. As such, clinicians caring for these women had an additional, and important, feature used in the overall assessment of fetal wellbeing. Secondly, all four studies included women in either spontaneous or induced labour. In some practice contexts, the admission CTG is performed in the absence of a diagnosis of labour, i.e. an admission CTG is done before an assessment to diagnose labour is made. Thirdly, in the Mitchell 2008, women allocated to admission CTG received a routine 15-minute CTG. This is less than the 20 minutes recommended for visual assessment of FHR reactivity by some guidelines (RCOG 2001). These points should be considered in determining the applicability of the evidence presented here to different practice contexts.

It is reasonable to assume that outcomes related to perinatal death are perhaps those of most importance to women and maternity care professionals. In this review, there was no significant difference in perinatal mortality between admission CTG and intermittent auscultation. However, to identify correctly a 20% reduction in proportion of perinatal deaths (assuming a developed world rate of seven per 1000) between admission CTG and intermittent auscultation, a sample size of more than 100,000 is required (with $\alpha = 0.05$, $\beta - 1 = 20\%$) and even then a 20% reduction might be regarded as optimistic, with lower effect sizes requiring higher sample sizes. Such sample sizes are unlikely, except perhaps in the largest of mega-trials and, therefore, typical randomised trials and systematic reviews of these trials, including this review, have insufficient power to evaluate the effects of different fetal monitoring modalities on fetal and neonatal mortality measures. Therefore, while this review found no evidence of an effect for admission CTG on perinatal mortality, this should not be confused with ev-

idence of no effect.

There are important outcomes, though secondary, which are not reported, are unavailable or are not in a suitable format to be included in the analysis; these include perceived control and satisfaction with labour. This reflects a widespread tendency among the clinical and research community to frame outcomes in a non-salutogenic or pathological manner (e.g. operative birth) rather than in a salutogenic, wellbeing orientated manner (e.g. normal birth). It may also reflect the relative difficulty of quantifying outcomes that are subjective and difficult, although important, to 'measure'.

In addition to statistical heterogeneity, there is evidence of clinical heterogeneity between studies in the numbers of women having an epidural. In Impey 2003, significantly more women allocated to intermittent auscultation had an epidural compared with women allocated to admission CTG. This contrasts with Mires 2001, who found significantly fewer epidurals in women allocated to intermittent auscultation. The third study reporting on this outcome, Cheyne 2003, found no significant difference in epidurals between groups. It is difficult to explain such heterogeneity. All three studies found an increased rate of continuous EFM for women allocated to admission CTG, making it unlikely that differing practices in use of continuous EFM indications give rise to differential effects on epidural use. Furthermore, although the labours of nulliparous women in Impey 2003 were managed actively, the package of care for active management in labour has not been shown to impact on epidural rates (Brown 2008).

Overall, risk of bias of the four included studies was assessed as low across all domains assessed with the exception of blinded outcome assessment, which was unclear in one study (Mitchell 2008) and not carried out in another (Cheyne 2003). Of the 3752 women randomised during the third trimester in the study by Mires 2001, 37% developed an obstetric complication between randomisation and admission in labour that warranted continuous FHR monitoring in labour. Specific complications are given and these are in line with clinical norms reported in the literature. The study by Impey 2003 also included a small proportion of women with risk factors. Both Impey 2003 and Mires 2001 provided data for the sub-group of low-risk women, and these data are used in the main analyses in this review. Sensitivity analyses were done in which the outcomes for all randomised women were used. Results were consistent with the primary comparison effects, with the exception of two outcomes. Caesarean section became statistically significant, with significantly more women allocated to admission CTG having, on average, a caesarean section compared with women allocated to intermittent auscultation. Epidural also became significant, with significantly more women allocated to intermittent auscultation having, on average, an epidural compared with women allocated to admission CTG. However, these findings should be interpreted with caution. For the outcome caesarean section in whole-group comparison, Mires 2001 contributes most weight to the meta-analysis. However, in this study and as mentioned earlier,

37% (n = 704) of women randomised to intermittent auscultation developed complications during pregnancy and required admission CTG on admission.

AUTHORS' CONCLUSIONS

Implications for practice

Contrary to continued use in some clinical areas, we found no evidence of benefit for the use of the admission cardiotocograph (CTG) for low-risk women on admission in labour. Furthermore, the probability is that admission CTG increases the caesarean section rate by approximately 20%. The data lacked power to detect possible important differences in perinatal mortality. However, it is unlikely that any trial, or meta-analysis, will be adequately powered to detect such differences. The findings of this review supports recommendations that the admission CTG not be used for women who are low risk on admission in labour (Liston 2007; NCCWCH 2007; RCOG 2001). Women should be informed that admission CTG is likely associated with an increase in the incidence of caesarean section without evidence of benefit.

It is important to note that all four trials included in this review were conducted in developed Western European countries. The usefulness of the findings of this review for developing countries will depend on FHR monitoring practices. However, an absence of benefit and likely harm associated with admission CTG will have relevance for countries where questions are being asked about the role of the admission CTG.

Implications for research

All four included studies used the admission CTG on women in spontaneous or induced labour. Future studies evaluating the effects of the admission CTG should consider including women admitted with signs of labour and prior to a formal diagnosis of labour. This would include a cohort of women currently having admission CTGs and not included in current trials. The largest study in this review includes women where the colour of the liquor was known to be clear. Additional studies that evaluate the effects of the admission CTG on women where the colour of the amniotic fluid is not known are needed.

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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.

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- * Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cheyne 2003

Methods	Study design: RCT. Duration of study: 1999.	
Participants	Setting: Glasgow Royal Maternity Hospital, Scotland. Inclusion criteria: healthy women who had experienced a normal pregnancy, presented at term in spontaneous labour and were eligible for admission to the Midwives Birth Unit. Exclusion criteria: women with risk factors. Participants randomised: 334 women (157 admission CTG (referred to as 'control group' in paper), 177 intermittent auscultation (referred to as 'study group' in paper)) Randomisation on admission in labour.	
Interventions	Admission CTG: a routine 20-minute period of EFM at the time of admission. Intermittent auscultation: the fetal heart was auscultated during and immediately following a contraction for a minimum of 60 seconds	
Outcomes	Outcomes considered in the review and reported in or extracted from the study: caesarean section; instrumental vaginal birth; continuous EFM during labour; amniotomy; oxytocin for augmentation of labour; epidural; fetal blood sampling; fetal and neonatal deaths; Apgar score < 7 at or after 5 minutes; admission to neonatal intensive care.	
Notes	Unpublished data to permit re-inclusion of women to groups as randomised kindly provided by author	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'...computer-generated in order to allocate participants equally between the two groups...'
Allocation concealment (selection bias)	Low risk	'...sequentially numbered, sealed opaque envelopes, which contained allocation to the appropriate group.'

Cheyne 2003 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: in the trial report 22 women (7%) are excluded from the analysis (21 women entered into the study and found not to be in labour and 1 randomisation card missing). However, data for these 21 of 22 women was identified and extracted subsequently by the trial author and kindly provided to the review team
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods section were reported adequately in results
Other bias	Low risk	None identified.
Overall risk of bias	Low risk	

Impey 2003

Methods	Study design: RCT. Duration of study: 1997-2001.
Participants	Setting: National Maternity Hospital in Dublin, Ireland. Inclusion criteria: women were eligible for inclusion if they were admitted in labour, a singleton pregnancy, fewer than 42 completed weeks of gestation, no suspicion or evidence of antenatal fetal compromise, no adverse obstetric history, clear amniotic fluid, and maternal temperature of 37.5°C or less at admission. Participants randomised: 8628 women (4320 admission CTG, 4308 intermittent auscultation) Randomisation on admission in labour. A relatively small number (< 5%) of women who had a previous caesarean section and who went into labour prior to 37 completed weeks' gestation were included in this study and were randomised. The trial author kindly provided data separately for the outcomes for women (i) between 37 and 42 completed weeks with (ii) an absence of previous caesarean section and these data are used in the main analyses in this review. Sensitivity analyses were done in which the outcomes for all randomised women were used
Interventions	Admission CTG: a 20-minute admission CTG immediately after early amniotomy done on diagnosis of labour in women presenting to the delivery ward Intermittent auscultation: intermittent auscultation was used for 1 minute after a contraction every 15 minutes in the first stage and every 5 minutes in the second stage of labour. This was done after early amniotomy on diagnosis of labour in women presenting to the delivery ward

Impey 2003 (Continued)

Outcomes	Outcomes considered in the review and reported in or extracted from the study: caesarean section; instrumental vaginal birth; continuous EFM during labour; oxytocin for augmentation of labour; epidural; fetal blood sampling; fetal and neonatal deaths; Apgar score < 7 at or after 5 minutes; neonatal seizures; admission to neonatal intensive care; length of stay in neonatal intensive care (hours).	
Notes	See <i>Participants</i> above.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'...the randomisation sequence was from a commercial package 10 and used a fixed block size of 100. It was changed after 2621 patients had been recruited, and was generated by the National Perinatal Epidemiology Unit with random block sizes of 100-250.'
Allocation concealment (selection bias)	Low risk	'...sealed, opaque, sequentially numbered envelope.'
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'...Data were entered and neonatal assessment was made without knowledge of the randomised assignment.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 22 (0.5%); admission CTG 26 (0.6%). Intermittent auscultation For outcome 'pH less than 7 or BD/E (Base Deficit/Excess) > than 12 mmol/L' 7.5% and 7.8% data missing for admission CTG and intermittent auscultation respectively
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods section were reported adequately in results
Other bias	Low risk	None identified.
Overall risk of bias	Low risk	

Mires 2001

Methods	Study design: RCT. Duration of study: not stated.	
Participants	Setting: Dundee, Scotland. Inclusion criteria: 'Women were eligible to join the study if they were booked for hospital delivery, attended a hospital or community based consultant led clinic in the third trimester of pregnancy, and had no obstetric complications at that visit that would warrant continuous intrapartum monitoring of FHR (pre eclampsia or hypertension in previous or index pregnancy; essential hypertension; diabetes (insulin dependent or gestational); suspected intrauterine growth restriction; placental abruption or praevia or vaginal bleeding of unknown origin; multiple pregnancy; fetal malformation; previous caesarean section; breech presentation; or rhesus isoimmunisation).' Participants randomised: 3752 women randomised. 'No data collected n = 1' (1866 admission CTG, 1885 intermittent auscultation) A total of 3752 women were recruited to the study and randomised during the third trimester. However, some women developed an obstetric complication between randomisation and admission in labour that warranted continuous FHR monitoring in labour, such that only 2367 women were judged to be low-risk when in labour (1186 admission CTG, 1181 intermittent auscultation). The trial author kindly provided data separately for the outcomes in this subgroup of women and these data are used in the main analyses in this review. Sensitivity analyses were done in which the outcomes for all randomised women were used	
Interventions	Admission CTG: a 20-minute CTG on admission in spontaneous uncomplicated labour Intermittent auscultation: auscultation of the fetal heart with a hand held Doppler device during and immediately after at least 1 contraction	
Outcomes	Outcomes considered in the review and reported in or extracted from the study: caesarean section; instrumental vaginal birth; continuous EFM during labour; amniotomy; oxytocin for augmentation of labour; epidural; fetal blood sampling; fetal and neonatal deaths; evidence of fetal multi-organ compromise within the first 24 hours after birth; Apgar score < 7 at or after 5 minutes; hypoxic ischaemic encephalopathy; admission to neonatal intensive care; length of stay in neonatal intensive care (days).	
Notes	See <i>Participants</i> above.	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Mires 2001 (Continued)

Random sequence generation (selection bias)	Low risk	'...commercially available computer randomisation program.'
Allocation concealment (selection bias)	Low risk	'The allocation was placed in a sealed envelope...'
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'The data analysts were blind to the randomisation code.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up for the primary outcome of metabolic acidosis was high (admission CTG n = 310, 26% and intermittent auscultation n = 321, 27%). However, metabolic acidosis was defined as 'pH less than 7.20 or BD (Base Deficit) > than 8 mmol/L'. Data were unavailable for the outcome metabolic acidosis as defined in this review, i.e. 'pH less than 7 or BD/E (Base Deficit/Excess) > than 12 mmol/L', therefore this study does not provide data for this outcome in this review. All other outcomes had low rates of missing data, hence rating as 'low risk of bias'
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods section were reported adequately in results
Other bias	Low risk	'Between randomisation during the third trimester of pregnancy and admission in labour, 1384 women (37%) developed an obstetric complication that warranted continuous fetal heart rate monitoring in labour' A total of 3752 women were recruited to the study and randomised during the third trimester. However, some women developed complications between randomisation and admission in labour, such that only 2367 women were judged to be low risk when in labour (1186 admission CTG, 1181 intermittent auscultation). There are similar levels of attrition in both groups due to development of complications suggesting that allocation concealment remained intact. The trial author kindly provided data separately for the outcomes in this low-risk subgroup of women and these data are

Mires 2001 (Continued)

		used in the main analyses in this review
Overall risk of bias	Low risk	

Mitchell 2008

Methods	Study design: RCT. Duration of study: 2002-2006.	
Participants	Setting: Buckinghamshire, England. Inclusion criteria: labouring women considered to be 'low risk' of fetal or maternal complications on admission Exclusion criteria: any minor maternal medical complication, e.g. diabetes or essential hypertension; previous caesarean section; preterm labour (less than 37 completed weeks); multiple pregnancy; prolonged pregnancy (more than 42 completed weeks); prolonged membrane rupture (more than 24 hours); induction of labour; meconium-stained liquor; maternal pyrexia; rhesus sensitisation; polyhydramnios; oligohydramnios; pre-eclampsia or blood pressure over 140/90 mmHg; abnormal presentation or lie (e.g. breech, transverse); high head (5/5ths palpable per abdomen); antepartum or intrapartum haemorrhage; known or suspected intrauterine growth retardation; any known or suspected fetal medical complication; abnormal Doppler artery velocimetry; known fetal malformation; poor obstetric history (e.g. history of stillbirth); un-booked. Participants randomised: 582 women randomised (298 admission CTG, 284 intermittent auscultation) Randomisation on admission in labour.	
Interventions	Admission CTG: a 15-minute CTG on admission in spontaneous uncomplicated labour Intermittent auscultation: auscultation of the fetal heart for one continuous minute using a Pinard stethoscope or Doppler ultrasound device, after a contraction, at least every 15 minutes in the first stage of labour, and every 5 minutes in the second stage of labour	
Outcomes	Outcomes considered in the review and reported in or extracted from the study: caesarean section; instrumental vaginal birth; oxytocin for augmentation of labour; fetal and neonatal deaths; Apgar score < 7 at or after 5 minutes; admission to neonatal intensive care.	
Notes	See <i>Participants</i> above.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'...via a random number table.'

Mitchell 2008 (Continued)

Allocation concealment (selection bias)	Low risk	'Allocation to control and experimental arms was via opening of the next envelope in a series of sequentially numbered envelopes.'
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcome data reported with exception of 'augmentation with oxytocin' where missing data were low (admission CTG n = 2, 0.7% and intermittent auscultation n = 4, 1.4%)
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods section were reported adequately in results
Other bias	Low risk	None identified.
Overall risk of bias	Low risk	

CTG: cardiotocograph

EFM: electronic fetal monitoring

FHR: fetal heart rate

RCT: randomised controlled trial

Characteristics of ongoing studies [ordered by study ID]

Devane 2008

Trial name or title	Foetal cardiotocography versus intermittent auscultation during labour ward admission: a randomised controlled trial (the ADCAR trial)
Methods	Randomised controlled trial.
Participants	<ol style="list-style-type: none"> 1. Women between 37+0 and 40+6 completed weeks of pregnancy. 2. Absence of antenatal, maternal and foetal risk factors to the development of neonatal encephalopathy, cerebral palsy or perinatal death as per Royal College of Obstetricians and Gynaecologists (2001), which warrant EFM. 3. Greater than or equal to 18 years. 4. Ability to understand study information and willingness to give written, informed consent. 5. Women participating in interviews must be able to converse in English
Interventions	<ol style="list-style-type: none"> 1. Control: 20-minute CTG on admission to labour ward/assessment room with signs of labour. 2. Intervention: intermittent auscultation of the fetal heart, on admission to the labour ward/assessment room

Devane 2008 (Continued)

	with signs of labour, using a Pinard stethoscope or a Doppler ultrasound device
Outcomes	Primary: incidence of caesarean section.
Starting date	2008.
Contact information	Declan Devane declan.devane@nuigalway.ie
Notes	

CTG: cardiotocograph

EFM: electronic fetal monitoring

DATA AND ANALYSES

Comparison 1. Admission cardiotocography versus Intermittent auscultation (low-risk women)

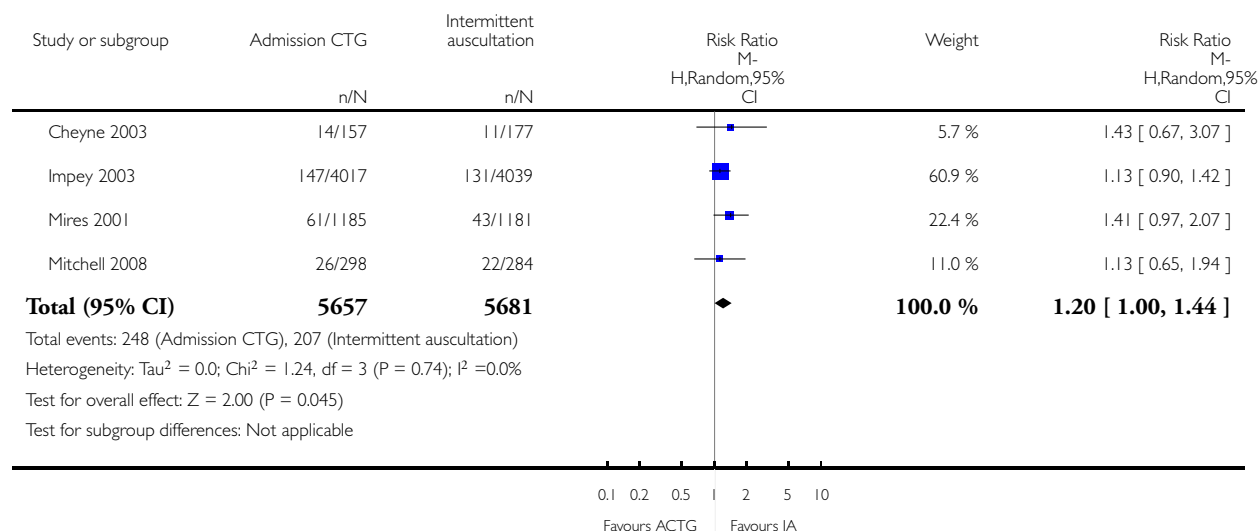
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	4	11338	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.00, 1.44]
2 Instrumental vaginal birth	4	11338	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.95, 1.27]
3 Continuous EFM during labour	3	10753	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.14, 1.48]
4 Amniotomy	2	2694	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.97, 1.12]
5 Oxytocin for augmentation of labour	4	11324	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.95, 1.17]
6 Epidural	3	10757	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.87, 1.41]
7 Fetal blood sampling	3	10757	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.13, 1.45]
8 Fetal and neonatal deaths	4	11339	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.30, 3.47]
9 Evidence of fetal multi-organ compromise within the first 24 hours after birth	1	8056	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.19, 1.67]
10 Admission to neonatal intensive care	4	11331	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.86, 1.24]
11 Apgar score < 7 at or after 5 minutes	4	11324	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.54, 1.85]
12 Hypoxic ischaemic encephalopathy	1	2367	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.37, 3.90]
13 Neonatal seizures	1	8056	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.32, 1.61]
14 Length of stay in neonatal intensive care (days)	1	91	Mean Difference (IV, Random, 95% CI)	1.80 [-0.59, 4.19]
15 Length of stay in neonatal intensive care (hours)	1	318	Mean Difference (IV, Random, 95% CI)	6.20 [-8.70, 21.10]

Analysis 1.1. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 1 Caesarean section.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 1 Caesarean section

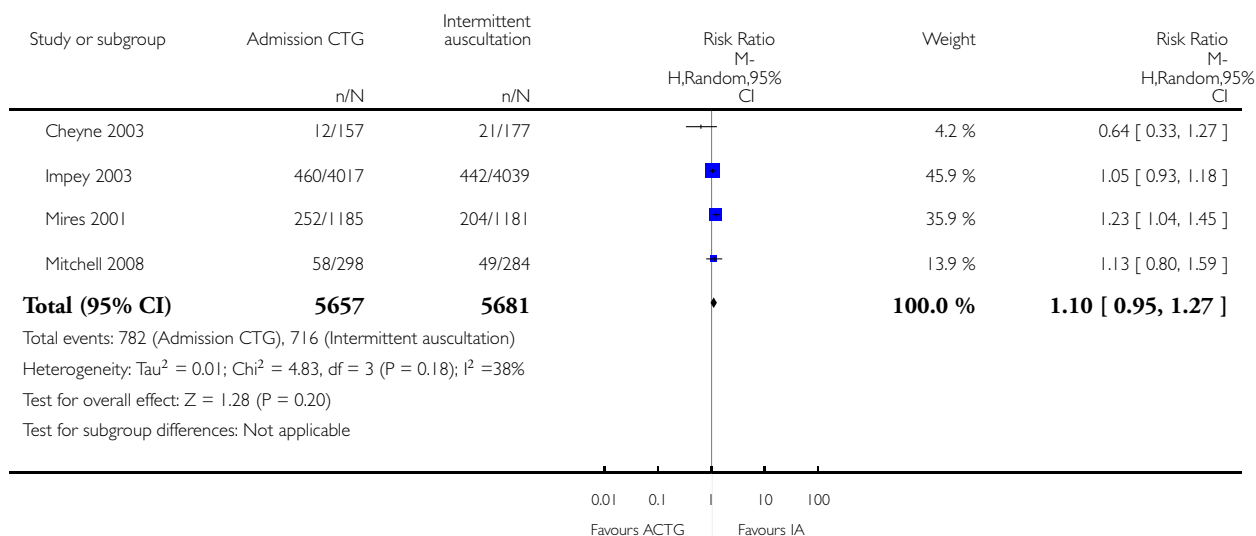


Analysis 1.2. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 2 Instrumental vaginal birth.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 2 Instrumental vaginal birth

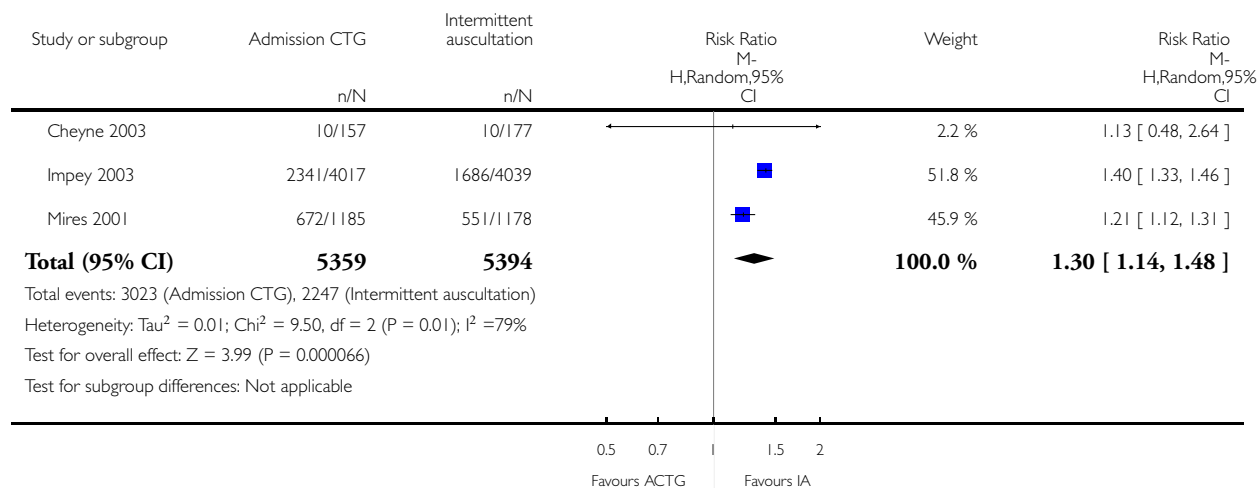


Analysis 1.3. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 3 Continuous EFM during labour.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 3 Continuous EFM during labour

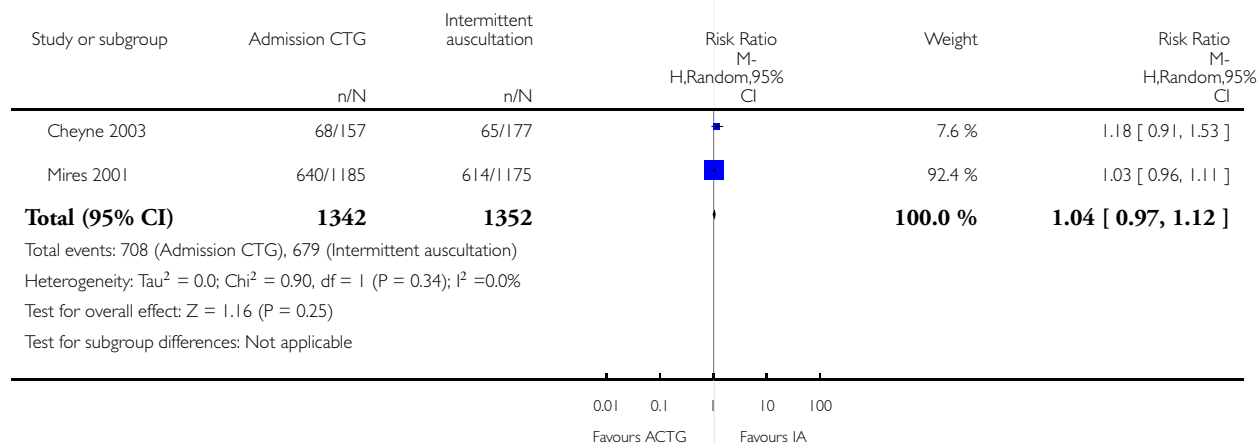


Analysis 1.4. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 4 Amniotomy.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 4 Amniotomy

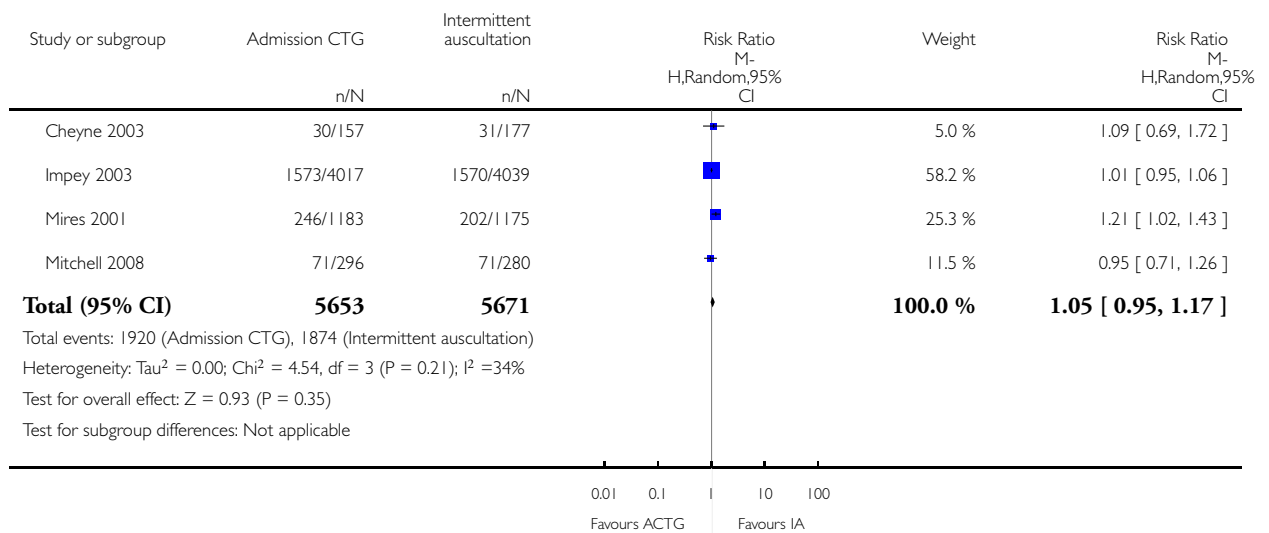


Analysis 1.5. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 5 Oxytocin for augmentation of labour.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 5 Oxytocin for augmentation of labour

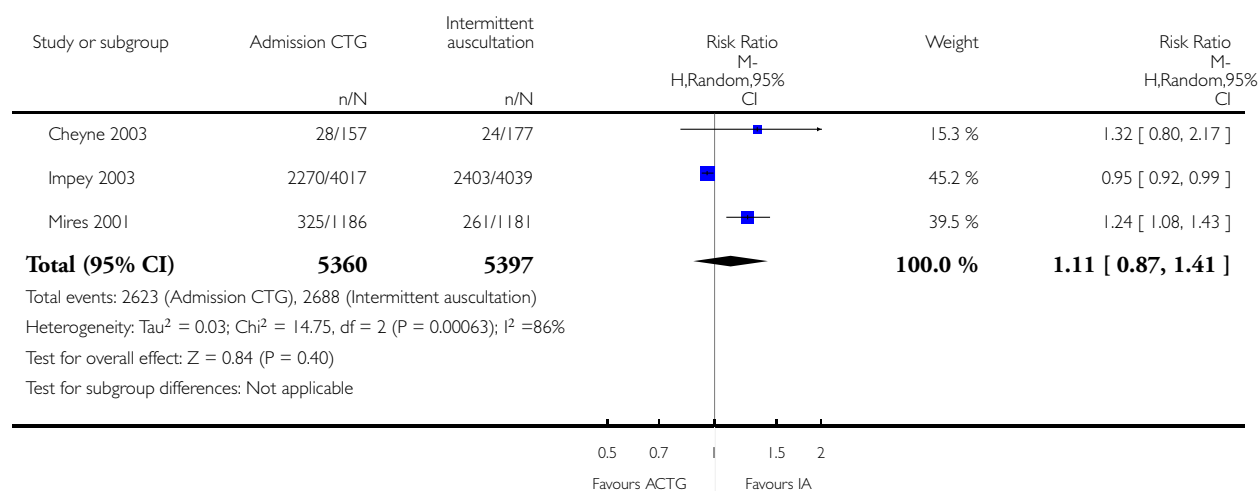


Analysis 1.6. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 6 Epidural.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 6 Epidural

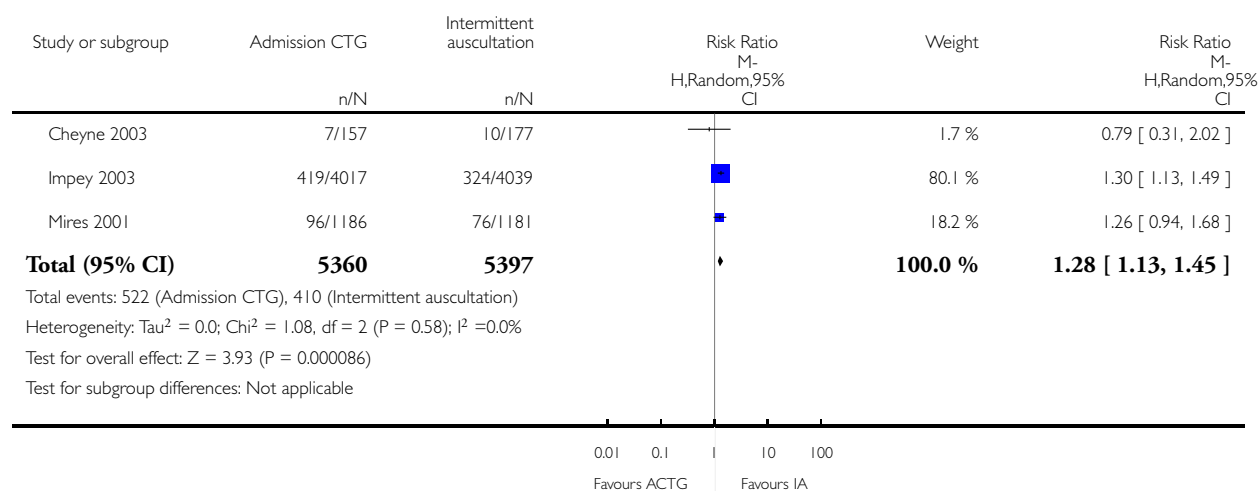


Analysis 1.7. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 7 Fetal blood sampling.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 7 Fetal blood sampling

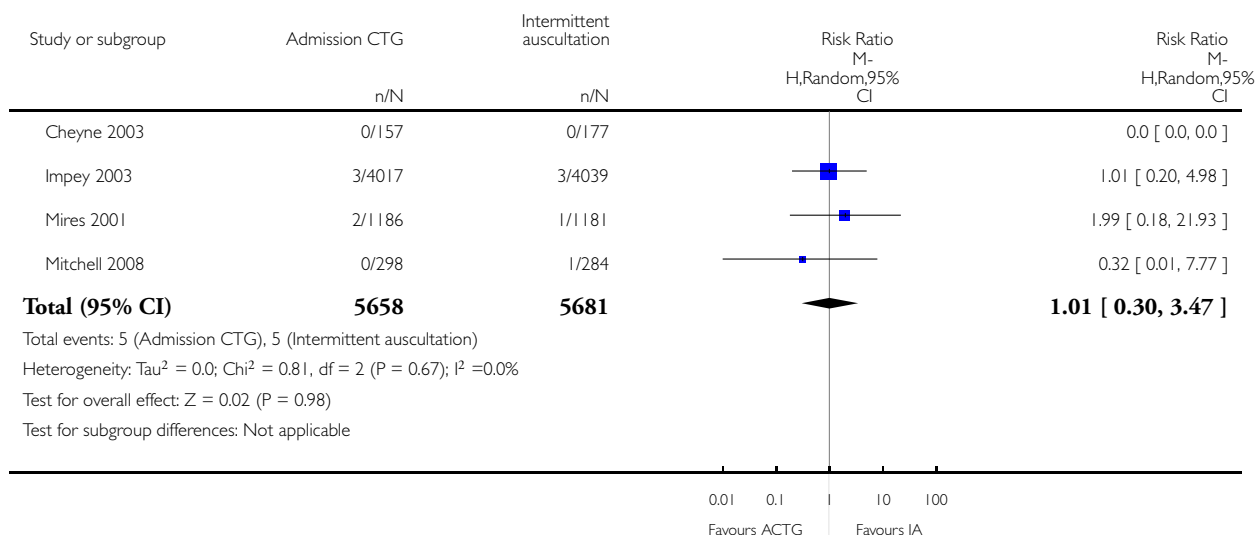


Analysis 1.8. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 8 Fetal and neonatal deaths.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 8 Fetal and neonatal deaths

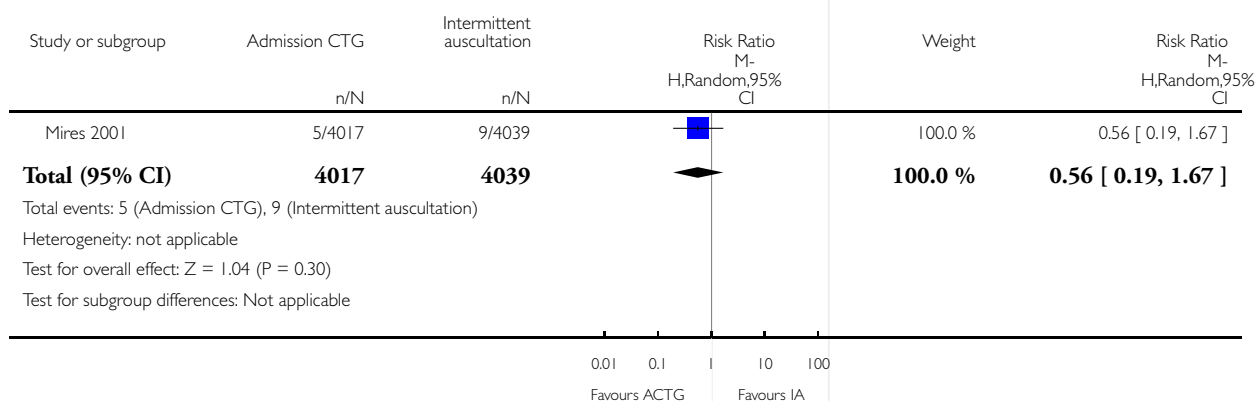


Analysis 1.9. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 9 Evidence of fetal multi-organ compromise within the first 24 hours after birth.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 9 Evidence of fetal multi-organ compromise within the first 24 hours after birth

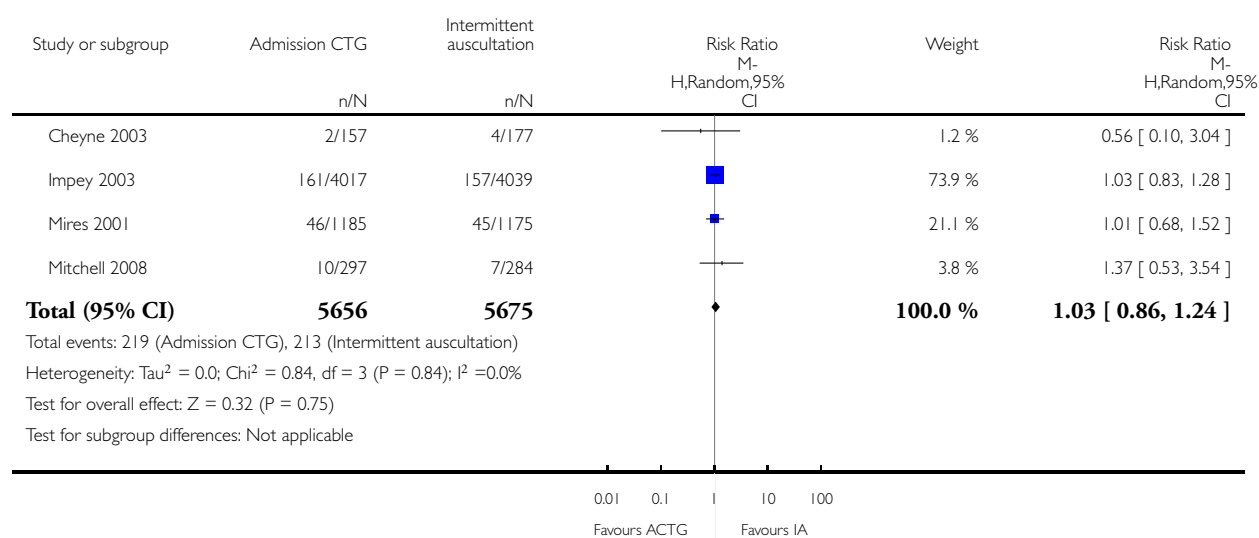


Analysis 1.10. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 10 Admission to neonatal intensive care.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 10 Admission to neonatal intensive care

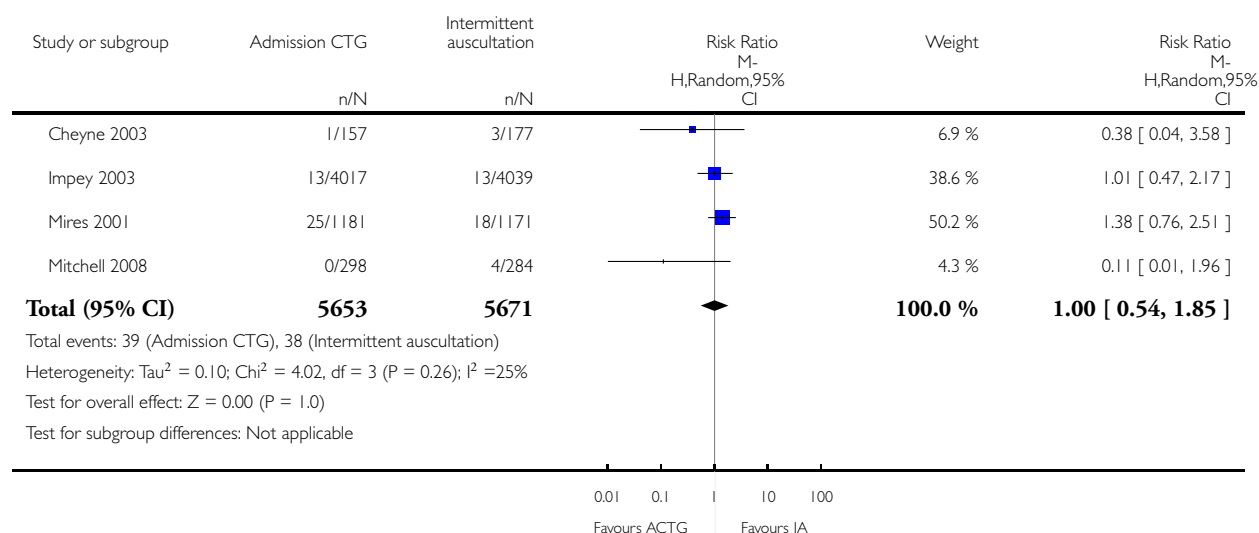


Analysis 1.11. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 11 Apgar score < 7 at or after 5 minutes.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 11 Apgar score < 7 at or after 5 minutes

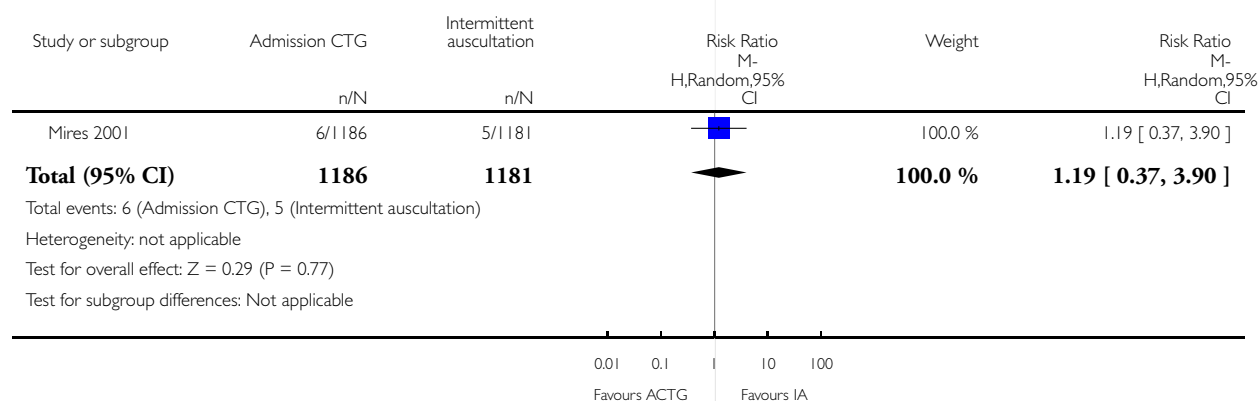


Analysis 1.12. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 12 Hypoxic ischaemic encephalopathy.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 12 Hypoxic ischaemic encephalopathy

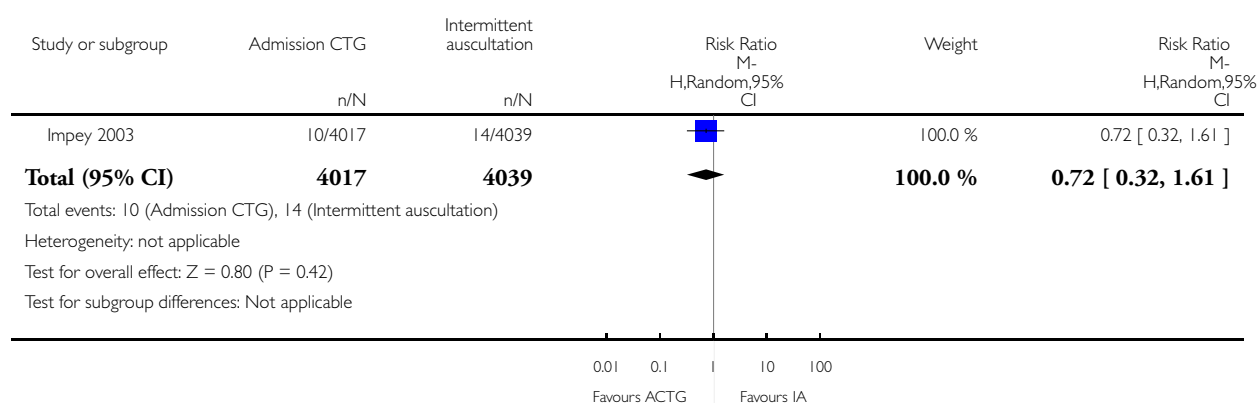


Analysis I.13. Comparison I Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome I3 Neonatal seizures.

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: I Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: I3 Neonatal seizures

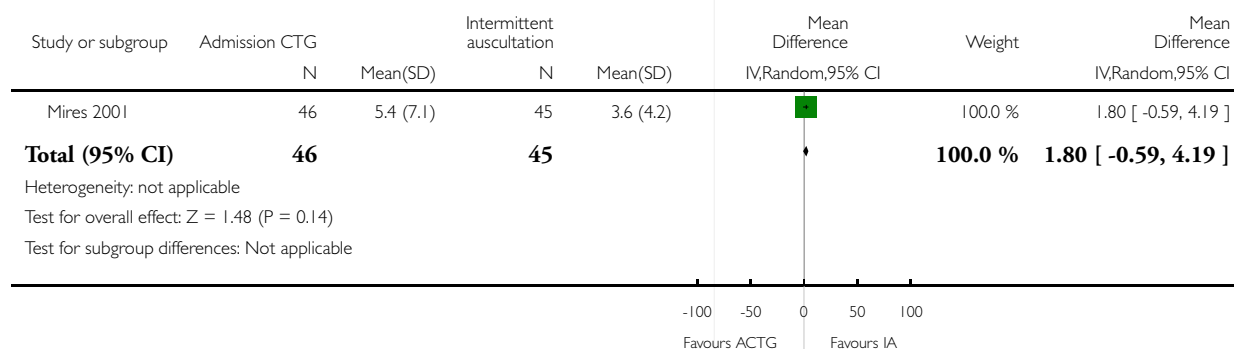


Analysis I.14. Comparison I Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome I4 Length of stay in neonatal intensive care (days).

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: I Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: I4 Length of stay in neonatal intensive care (days)

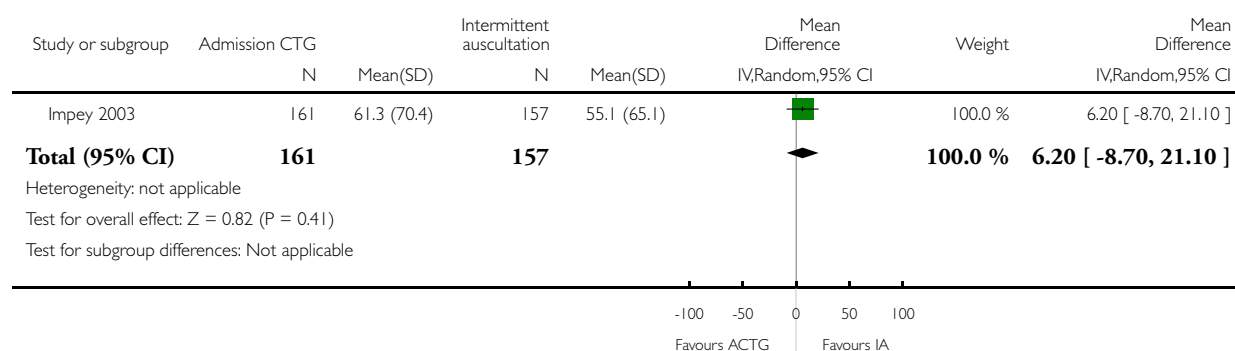


Analysis 1.15. Comparison 1 Admission cardiotocography versus Intermittent auscultation (low-risk women), Outcome 15 Length of stay in neonatal intensive care (hours).

Review: Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing

Comparison: 1 Admission cardiotocography versus Intermittent auscultation (low-risk women)

Outcome: 15 Length of stay in neonatal intensive care (hours)



APPENDICES

Appendix I. Search strategies

CENTRAL, MEDLINE and CINAHL

1 cardiotoc\$.af.

2 auscultat\$.af.

3 1 and 2

4 exp Fetal Monitoring/

5 admission.af.

6 exp Labor, Obstetric/

7 (labor or labour).mp.

8 6 or 7

9 4 and 5 and 8

10 3 or 9

EMBASE

1 cardiotoc\$.mp

2 auscultat\$.mp

3 1 and 2

4 Fetus Monitoring/

5 admission.mp

6 labor or labour.mp

7 4 and 5 and 6

8 3 or 7

We used the free text terms from the strategies above to search Dissertation Abstracts (1980 to 17 May 2011)

HISTORY

Protocol first published: Issue 1, 2005

Review first published: Issue 2, 2012

Date	Event	Description
7 July 2010	New citation required and major changes	Protocol substantially updated and reinstated.
11 November 2009	Amended	Protocol withdrawn from publication.
12 May 2009	Amended	Contact details updated.
31 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Declan Devane (DD) and Valerie Smith (VS) drafted the background section and all other authors contributed to editing the text. All authors contributed to the drafting of the inclusion criteria for the review. DD added the methodology section with other authors commenting. DD, VS and Joan G. Lalor (JGL) abstracted and pooled data. DD wrote the results section, discussion and implications sections with input from all authors.

DECLARATIONS OF INTEREST

Declan Devane and Valerie Smith are currently conducting a trial, known as the ADCAR Trial, evaluating the effectiveness of the admission cardiotocograph (CTG) compared with intermittent auscultation. This study is funded by the Health Research Board (Ireland). If this trial is eligible for inclusion in the full review, or a subsequent review update, the investigators will not be involved in assessing the trial for inclusion, assessing risk of bias, or data extraction. These tasks will be carried out by two other members of the review team who are not directly involved with the ADCAR Trial.

Declan Devane has acted as an expert midwifery witness in legal cases centred around aspects of fetal monitoring and has been paid for same. Declan provides and has been paid to deliver fetal monitoring education programmes, which are organised by a commercial company who provide, among other products, CTG machines. The company do not vet nor have any other input into the content of the programmes.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Health Research Board, Ireland.

Declan Devane and Valerie Smith are currently conducting a trial, known as the ADCAR Trial, evaluating the effectiveness of the admission CTG compared with intermittent auscultation.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Additional post-hoc sensitivity analyses have been conducted beyond those stated in the protocol. These have been identified clearly as post-hoc analyses.