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[Intervention Review]

Fetal electrocardiogram (ECG) for fetal monitoring during labour

James P Neilson¹¹Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK**Contact:** James P Neilson, Department of Women's and Children's Health, The University of Liverpool, First Floor, Liverpool Women's NHS Foundation Trust, Crown Street, Liverpool, L8 7SS, UK. jneilson@liverpool.ac.uk.**Editorial group:** Cochrane Pregnancy and Childbirth Group.**Publication status and date:** New search for studies and content updated (no change to conclusions), published in Issue 12, 2015.**Citation:** Neilson JP. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *Cochrane Database of Systematic Reviews* 2015, Issue 12. Art. No.: CD000116. DOI: [10.1002/14651858.CD000116.pub5](https://doi.org/10.1002/14651858.CD000116.pub5).

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ABSTRACT

Background

Hypoxaemia during labour can alter the shape of the fetal electrocardiogram (ECG) waveform, notably the relation of the PR to RR intervals, and elevation or depression of the ST segment. Technical systems have therefore been developed to monitor the fetal ECG during labour as an adjunct to continuous electronic fetal heart rate monitoring with the aim of improving fetal outcome and minimising unnecessary obstetric interference.

Objectives

To compare the effects of analysis of fetal ECG waveforms during labour with alternative methods of fetal monitoring.

Search methods

The Cochrane Pregnancy and Childbirth Group's Trials Register (latest search 23 September 2015) and reference lists of retrieved studies.

Selection criteria

Randomised trials comparing fetal ECG waveform analysis with alternative methods of fetal monitoring during labour.

Data collection and analysis

One review author independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy. One review author assessed the quality of the evidence using the GRADE approach.

Main results

Seven trials (27,403 women) were included: six trials of ST waveform analysis (26,446 women) and one trial of PR interval analysis (957 women). The trials were generally at low risk of bias for most domains and the quality of evidence for ST waveform analysis trials was graded moderate to high. In comparison to continuous electronic fetal heart rate monitoring alone, the use of adjunctive ST waveform analysis made no obvious difference to primary outcomes: births by caesarean section (risk ratio (RR) 1.02, 95% confidence interval (CI) 0.96 to 1.08; six trials, 26,446 women; *high quality evidence*); the number of babies with severe metabolic acidosis at birth (cord arterial pH less than 7.05 and base deficit greater than 12 mmol/L) (average RR 0.72, 95% CI 0.43 to 1.20; six trials, 25,682 babies; *moderate quality evidence*); or babies with neonatal encephalopathy (RR 0.61, 95% CI 0.30 to 1.22; six trials, 26,410 babies; *high quality evidence*). There were, however, on average fewer fetal scalp samples taken during labour (average RR 0.61, 95% CI 0.41 to 0.91; four trials, 9671 babies; *high quality evidence*) although the findings were heterogeneous and there were no data from the largest trial (from the USA). There were marginally fewer operative vaginal births (RR 0.92, 95% CI 0.86 to 0.99; six trials, 26,446 women); but no obvious difference in the number of babies with low Apgar scores at five minutes or babies requiring neonatal intubation, or babies requiring admission to the special care unit (RR 0.96, 95% CI 0.89 to 1.04, six trials, 26,410 babies; *high quality evidence*). There was little evidence that monitoring by PR interval analysis conveyed any benefit of any sort.

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Authors' conclusions

The modest benefits of fewer fetal scalp samplings during labour (in settings in which this procedure is performed) and fewer instrumental vaginal births have to be considered against the disadvantages of needing to use an internal scalp electrode, after membrane rupture, for ECG waveform recordings. We found little strong evidence that ST waveform analysis had an effect on the primary outcome measures in this systematic review.

There was a lack of evidence showing that PR interval analysis improved any outcomes; and a larger future trial may possibly demonstrate beneficial effects.

There is little information about the value of fetal ECG waveform monitoring in preterm fetuses in labour. Information about long-term development of the babies included in the trials would be valuable.

PLAIN LANGUAGE SUMMARY

Fetal electrocardiogram (ECG) for fetal monitoring during labour

Monitoring the baby's heart using electrocardiography (ECG) plus cardiotocography (CTG) during labour provides some modest help for mothers and babies when continuous monitoring is needed.

Strong uterine contractions during labour reduce the flow of maternal blood to the placenta. The umbilical cord may also be compressed during labour, especially if the membranes are ruptured. Usually the baby has sufficient reserve to withstand this effect but some may become distressed. Electronic heart monitoring may be suggested if the doctors think the baby is not getting enough oxygen during labour. Two different methods may be used. CTG measures the baby's heart rate together with the mother's uterine contractions. An ECG measures the heart's electrical activity and the pattern of the heart beats. This involves an electrode being passed through the woman's cervix and attached to the baby's head. This review of seven randomised controlled trials, including a total of 27,403 women, found that monitoring the baby using ECG plus CTG resulted in fewer blood samples needing to be taken from the baby's scalp, and less surgical assistance with the birth, than with CTG alone. There was no difference in the number of caesarean deliveries and little to suggest that babies were in better condition at birth. The evidence was found to be of high quality.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Fetal electrocardiogram (ECG) (ST analysis) plus cardiotocography (CTG) versus CTG alone for fetal monitoring during labour

Fetal ECG (ST analysis) plus CTG versus CTG alone for fetal monitoring during labour

Patient or population: Pregnant women (and their fetuses) in labour, with a perceived need for continuous electronic fetal heart rate monitoring

Settings: Sweden, USA, Finland, France, The Netherlands, UK.

Intervention: Fetal ECG (ST analysis) plus CTG

Comparison: CTG alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of partici- pants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with CTG alone	Risk with Fetal ECG plus CTG				
Caesarean section - ST analysis	Study population		RR 1.02 (0.96 to 1.08)	26,446 (6 RCTs)	⊕⊕⊕⊕ high	
	135 per 1000	137 per 1000 (129 to 145)				
	Moderate					
	119 per 1000	121 per 1000 (114 to 128)				
Cord pH less than 7.05 and base deficit greater than 12 mmol/L - ST analysis	Study population		RR 0.72 (0.43 to 1.20)	25,682 (6 RCTs)	⊕⊕⊕⊖ moderate ¹	
	9 per 1000	7 per 1000 (4 to 11)				
	Moderate					
	11 per 1000	8 per 1000 (5 to 13)				
Neonatal encephalopathy - ST analysis	Study population		RR 0.61 (0.30 to 1.22)	26,410 (6 RCTs)	⊕⊕⊕⊕ high	
	2 per 1000	1 per 1000 (0 to 2)				
	Moderate					

	2 per 1000	1 per 1000 (1 to 2)			
Fetal blood sampling - ST analysis	Study population		RR 0.61 (0.41 to 0.91)	9671 (4 RCTs)	⊕⊕⊕⊕ high
	154 per 1000	94 per 1000 (63 to 140)			
	Moderate				
	131 per 1000	80 per 1000 (54 to 119)			
Operative vaginal delivery - ST analysis	Study population		RR 0.92 (0.86 to 0.99)	26,446 (6 RCTs)	⊕⊕⊕⊕ high
	113 per 1000	104 per 1000 (97 to 112)			
	Moderate				
	133 per 1000	122 per 1000 (114 to 131)			
Admission to neonatal special care unit - ST analysis	Study population		RR 0.96 (0.89 to 1.04)	26410 (6 RCTs)	⊕⊕⊕⊕ high
	88 per 1000	84 per 1000 (78 to 91)			
	Moderate				
	55 per 1000	53 per 1000 (49 to 57)			
Perinatal death - ST analysis	Study population		RR 1.71 (0.67 to 4.33)	26,446 (6 RCTs)	⊕⊕⊕⊕ high
	0 per 1000	1 per 1000 (0 to 2)			
	Moderate				
	0 per 1000	1 per 1000 (0 to 2)			

***The risk in the intervention group** (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: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Some heterogeneity in findings (I^2 55%)

BACKGROUND

Description of the condition

Labour poses a potential threat to fetal wellbeing. The supply of oxygen to the fetus requires an adequate supply of maternal blood to the placenta, a properly functioning placenta to allow transfer of oxygen from maternal to fetal blood, and a patent umbilical vein in the umbilical cord to the fetus. Strong uterine contractions in labour stop the flow of maternal blood to the placenta with intermittent decreases in oxygenation. Most fetuses have sufficient metabolic reserve to withstand this effect but those with limited reserves, notably malnourished 'growth restricted' fetuses, may become distressed. The umbilical cord may also be compressed during labour, especially if the membranes are ruptured, which may also cause distress.

Description of the intervention

The earliest method of monitoring fetal wellbeing during labour was by using the fetal (Pinard) stethoscope intermittently to calculate the fetal heart rate. During the 1960s and 1970s, electronic systems were developed to allow monitoring of the fetal heart rate together with the mother's uterine contractions (cardiotocography (CTG)), and these have been very widely used. To monitor the heart rate, signals can be obtained from an ultrasound transducer strapped to the mother's abdomen, or from an electrode clipped into the baby's scalp. Traces of the baby's heart rate may be 'continuous' (that is, throughout labour) or intermittent. Although the mother's mobility is limited by both methods, this is obviously greater with continuous monitoring. Non-reassuring features on a CTG trace would include unusually rapid or slow rates, a flat pattern (reduced variability), and certain types of heart rate decelerations (especially 'late' or 'severe variable' decelerations). Such observations might prompt further intervention in the form of operative delivery, or additional testing of fetal condition (see below).

A systematic review of randomised trials comparing continuous electronic fetal heart rate monitoring (CTG) and intermittent auscultation ([Alfirevic 2013](#)), showed fewer babies having neonatal convulsions after continuous monitoring (risk ratio (RR) 0.50, 95% confidence interval (CI) 0.31 to 0.80), but at the cost of increased rates of obstetric intervention in the form of caesarean section (RR 1.63, 95% CI 1.29 to 2.07) and instrumental vaginal delivery (RR 1.15, 95% CI 1.01 to 1.33). Neonatal convulsions are often, but not always, associated with hypoxic-ischaemic encephalopathy due to hypoxaemic brain damage and may be linked to subsequent neuro-developmental disability, including cerebral palsy. It should therefore be an important goal of obstetric care to avoid neonatal convulsions. However, it is also important to avoid unnecessary obstetric interventions.

Cardiotocographic traces may be difficult to interpret, resulting in unnecessary operative interventions, while some significant changes go unrecognised. Computerised CTG has not proved helpful during labour ([Dawes 1994](#)). Adjunctive tests have therefore been developed to be used alongside CTG, in an attempt to refine assessment of fetal wellbeing with the ultimate objective of decreasing unnecessary intervention without jeopardising fetal outcome. Fetal scalp sampling for pH or lactate estimation is the best established adjunctive technique, but it is an awkward, uncomfortable procedure for the mother and involves a stab

incision in the scalp of the fetus. This has limited its appeal and pre-empts its use in areas with a high prevalence of HIV infection. An additional drawback is that, by its nature, scalp sampling can only give intermittent information about fetal acid-base status.

To address these challenges in intrapartum fetal monitoring, technology has been developed to monitor the fetal electrocardiographic (ECG) waveform during labour. If shown helpful to either improve fetal outcome, or decrease unnecessary intervention, or both, this has the potential advantage of providing continuous information as well as being less invasive than fetal scalp sampling (although it is not non-invasive: requiring a signal obtained from an electrode embedded in the fetal scalp).

How the intervention might work

The fetal ECG, like the adult ECG, displays P, QRS, and T waves corresponding to electrical events in the heart during each beat. The P wave represents atrial contraction, QRS ventricular contraction, and T ventricular repolarisation. Two parts of the fetal ECG waveform have attracted attention from researchers: PR/RR relations and the ST waveform ([Greene 1999](#)). Normally there is a positive correlation between the PR interval (the time between the P wave and the R component of the QRS complex) and the RR interval, such that when the heart rate increases both PR and RR intervals shorten. In sheep experiments where the fetus was made hypoxaemic, a paradoxical effect was seen, in which the PR interval shortened despite lengthening of the RR interval ('bradycardia' or slowing of the heart rate). This led to the hypothesis that measurement of PR/RR relations might help distinguish between hypoxaemic and (less worrying) non-hypoxaemic decelerations of the human fetal heart rate during labour, thus refining assessment of fetal wellbeing.

Repolarisation of myocardial (heart muscle) cells is very sensitive to metabolic dysfunction, and may be reflected in changes of the ST waveform. Thus, in adults with myocardial infarction or exercise-induced angina pectoris from coronary artery disease, the ST segment may be elevated. Similar findings may be seen in fetal sheep under experimental conditions of moderate to severe hypoxaemia with an elevation of the ST segment and the T wave ([Greene 1987](#)). This change can be expressed as a ratio of T wave height to QRS height: the T/QRS ratio. Testing of a microprocessor-based system ([Rosen 1989](#)) in observational studies in humans suggested that assessment of a combination of fetal heart rate and ST waveform changes may be clinically useful ([Rosen 1991](#)).

Why it is important to do this review

It is important for clinical and economic reasons to establish whether or not fetal ECG waveform analysis is helpful in improving fetal outcome, or decreasing unnecessary intervention, or both.

OBJECTIVES

To compare the effects of analysis of fetal electrocardiogram (ECG) waveforms during labour with alternative methods of fetal monitoring.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials that compare analysis of any component of the fetal electrocardiogram (ECG) during labour with alternative fetal monitoring methods. Studies using quasi-random methods of allocation (for example, alternation) were not included.

Types of participants

Pregnant women (and their fetuses) in labour, with a perceived need for continuous electronic fetal heart rate monitoring (for reasons, see [Characteristics of included studies](#) table).

Types of interventions

Any type of fetal electrocardiographic waveform analysis, alone or in combination with another method of fetal assessment.

Types of outcome measures

Primary outcomes

Maternal

1. Caesarean section

Fetal

1. Cord artery pH less than 7.05 and base deficit greater than 12 mmol/L
2. Neonatal encephalopathy

Secondary outcomes

Maternal

1. Fetal blood sampling
2. Operative vaginal delivery

Fetal

1. Apgar score less than seven at five minutes
2. Neonatal intubation
3. Admission to neonatal special care unit
4. Perinatal death
5. Cerebral palsy

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

The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Co-ordinator (23 September 2015).

For full search methods used to populate the Pregnancy and Childbirth Group Trials Register including the detailed 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, please follow this link to the editorial information about the [Cochrane Pregnancy and Childbirth Group](#) in *The Cochrane Library* and select

the '**Specialized Register**' section from the options on the left side of the screen.

Briefly, 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.

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth Group review topic (or topics), and is then added to the Register. The Trials Search Co-ordinator searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections (Included, Excluded, Awaiting Classification or Ongoing).

Searching other resources

The reference lists of retrieved studies were checked and no language or date restrictions were applied to the search.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, see [Neilson 2013](#).

The following methods were used for this update.

Selection of studies

Jim Neilson (JPN) assessed for inclusion all the potential studies identified as a result of the search strategy.

Data extraction and management

A form was designed to extract data. For eligible studies, JPN extracted the data using the agreed form. Data were entered into Review Manager software ([RevMan 2014](#)) and checked for accuracy.

When information regarding any of the above was unclear, JPN contacted the authors of the original reports to provide further details.

Assessment of risk of bias in included studies

The risk of bias for each study was assessed by JPN, using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

(1) Random sequence generation (checking for possible selection bias)

The review author describes 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.

The methods were assessed as:

- 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);
- unclear.

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

The review author describes for each included study the method used to conceal the allocation sequence to determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

The methods were assessed 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)

The review author describes for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Studies were considered to be at low risk of bias if they were blinded, or if it was judged that the lack of blinding could not have affected the results. Blinding was assessed separately for different outcomes or classes of outcomes.

The methods were assessed 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)

The review author describes for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or classes of outcomes.

The methods used to blind outcome assessment were assessed as:

- low, high or unclear risk of bias.

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

The review author describes for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis, including 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

supplied by the trial authors, these missing data were re-included in the analyses which were undertaken. The methods were assessed as:

- low risk of bias (less than 20% missing data);
- high risk of bias (greater than 20% missing data);
- unclear risk of bias.

(5) Selective reporting bias

The review author describes for each included study how he investigated the possibility of selective outcome reporting bias and what he found.

The methods were assessed 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 sources of bias

The review author describes for each included study any important concerns about other possible sources of bias.

The review author 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 was risk of other bias.

(7) Overall risk of bias

The review author made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, he assessed the likely magnitude and direction of the bias and whether he considered it likely to impact on the findings. In future updates, the impact of the level of bias will be explored through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the quality of the evidence using the GRADE approach

For this update the quality of the evidence was assessed 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 for the main comparison, fetal ECG plus CTG versus CTG alone, relating to the ST segment.

1. Caesarean section
2. Cord artery pH less than 7.05 and base deficit greater than 12 mmol/L
3. Neonatal encephalopathy
4. Fetal blood sampling
5. Operative vaginal delivery

6. Admission to neonatal special care unit
7. Perinatal death

GRADEpro Guideline Development Tool was used 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, results are presented as summary risk ratio with 95% confidence intervals.

Continuous data

No data were analysed as continuous data. In future updates, if appropriate, we will use the mean difference if outcomes are measured in the same way between trials. 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 for inclusion. In future updates, cluster-randomised trials will be included in the analyses along with individually-randomised trials. We will adjust their standard errors using the methods described in the *Handbook* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If ICCs are used from other sources, this will be reported and sensitivity analyses will be conducted to investigate the effect of variation in the ICC. If both cluster-randomised trials and individually-randomised trials are identified, the relevant information will be synthesised. It will be considered 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.

Heterogeneity in the randomisation unit will be acknowledged and a sensitivity analysis will be performed to investigate the effects of the randomisation unit.

Cross-over trials

If, in future updates of this review, if cross-over trials are identified on this topic, and such trials are deemed eligible for inclusion, they will be included in the analyses with parallel group trials, using methods described by [Elbourne 2002](#).

Dealing with missing data

For included studies, levels of attrition were noted. The impact of including studies with high levels of missing data in the overall

assessment of treatment effect will be explored in future updates by using sensitivity analysis.

For all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis, i.e. the review author attempted to include all participants randomised to each group in the analyses, and all participants were analysed 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

Statistical heterogeneity was assessed in each meta-analysis using the τ^2 , I^2 and χ^2 statistics. Heterogeneity was regarded as substantial if the I^2 was greater than 30% and either the τ^2 was greater than zero, or there was a low P value (less than 0.10) in the χ^2 test for heterogeneity.

Assessment of reporting biases

Had there been 10 or more studies in the meta-analysis, the review author planned to investigate reporting biases (such as publication bias) using funnel plots. In future updates, funnel plot asymmetry will be assessed visually. If asymmetry is suggested by a visual assessment, exploratory analyses will be performed to investigate it.

Data synthesis

Statistical analysis was carried out using Review Manager software ([RevMan 2014](#)). Fixed-effect meta-analyses were used 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. If there was clinical heterogeneity, sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, random-effects meta-analysis was used to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average of the range of possible treatment effects and the review author discusses the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, trials were not combined.

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

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was not carried out.

The review author carried out separate comparisons for two subgroups: based on whether the technique trialled assessed PR/RR relations or the ST segment. All outcomes were assessed in both groups of comparisons.

Sensitivity analysis

In future updates of this review, sensitivity analyses will be performed to explore outcomes with statistical heterogeneity and

the effects of any assumptions made, such as the value of the ICC used for cluster-randomised trials (if appropriate).

RESULTS

Description of studies

A total of seven trials involving 27,403 women were identified that fulfilled the criteria for inclusion (Amer-Wahlin 2001; Belfort 2015; Ojala 2006; Strachan 2000; Vayssiere 2007; Westerhuis 2010; Westgate 1993).

Results of the search

The updated search retrieved five new reports (four trials), one was included in this 2015 update (Belfort 2015); one was excluded (Ignatov 2012); one is awaiting classification (Gongora 2014); and one is ongoing (Bach 2012).

Included studies

Out of the seven trials included, six were based on ST analysis (UK, Sweden, France, Finland, The Netherlands, USA) and one on PR length (multi-national). See [Characteristics of included studies](#).

Excluded studies

Five studies were excluded. Two studies were not randomised controlled trials (Hruban 2006; Janku 2006), one study report was a review article (Olofsson 2003), one study did not involve analysis of fetal ECG waveform (Ignatov 2012), and one study was reported as abstract only with insufficient detail to include data (Prieto 2008).

Risk of bias in included studies

For a summary of all 'Risk of bias' assessments, please refer to [Figure 1](#); [Figure 2](#).

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Amer-Wahlin 2001	+	+	?	?	+	+	+
Belfort 2015	?	+	-	-	+	+	+
Ojala 2006	+	+	?	?	+	+	+
Strachan 2000	+	?	?	-	?	+	?
Vayssiere 2007	?	+	?	+	+	+	?
Westerhuis 2010	+	+	+	+	+	+	+
Westgate 1993	+	+	?	+	+	?	+

Allocation

Included trials were at low risk of selection bias.

Incomplete outcome data

Data were largely complete.

Blinding

Given the nature of the intervention, there was little scope for blinding women and their caregivers during labour. Blinding of observers who assessed the babies varied between studies.

Selective reporting

There was no suggestion of selective reporting.

Other potential sources of bias

There was no suggestion of other biases.

Effects of interventions

See: [Summary of findings for the main comparison Fetal electrocardiogram \(ECG\) \(ST analysis\) plus cardiotocography \(CTG\) versus CTG alone for fetal monitoring during labour](#)

Seven trials (27,403 women) were included: six trials of ST waveform analysis (26,446 women) and one trial of PR interval analysis (957 women).

Comparison: Fetal electrocardiogram (ECG) plus cardiotocography (CTG) versus CTG alone

Primary outcomes

Seven trials (27,403 women) were included: six trials of ST waveform analysis (26,446 women) and one trial of PR interval analysis (957 women). The quality of evidence for ST waveform analysis trials was moderate to strong. In comparison to continuous electronic fetal heart rate monitoring alone, the use of adjunctive ST waveform analysis made no obvious difference to primary outcomes: births by caesarean section (RR 1.02, 95% CI 0.96 to 1.08; data from 26,446 women, 6 trials), [Analysis 1.1](#); the number of babies with severe metabolic acidosis at birth (cord arterial pH less than 7.05 and base deficit greater than 12 mmol/L) (average RR 0.72, 95% CI 0.43 to 1.20; data from 25,682 babies, 6 trials; Heterogeneity: $I^2 = 55\%$, $\tau^2 = 0.21$), [Analysis 1.2](#); or babies with neonatal encephalopathy (RR 0.61, 95% CI 0.30 to 1.22; data from 26,410 babies, 6 trials), [Analysis 1.3](#).

Secondary outcomes

As for secondary outcomes, there were on average fewer fetal scalp samples taken during labour (average RR 0.61, 95% CI 0.41 to 0.91; data from 9671 babies, 4 trials; Heterogeneity: $I^2 = 92\%$, $\tau^2 = 0.15$), although the findings were heterogeneous and there were no data from the largest and most recent trial (from the USA), [Analysis 1.4](#); there were marginally fewer operative vaginal deliveries (RR 0.92, 95% CI 0.86 to 0.99; data from 26,446 women, 6 trials) [Analysis 1.5](#), but no obvious difference in the number of babies with low Apgar scores at five minutes (RR 0.95, 95% CI 0.73 to 1.24; data from 15302 babies, 5 trials) [Analysis 1.6](#); or babies requiring neonatal intubation (RR 1.37, 95% CI 0.89 to 2.11; data from 12544 babies, 2 trials) [Analysis 1.7](#), or babies requiring admission to the special care unit (RR 0.96, 95% CI 0.89 to 1.04; data from 26,410 babies, 6 trials) [Analysis 1.8](#). There were no differences in perinatal deaths (RR 1.71, 95% CI 0.67 to 4.33; data from 26,446 babies, 6 trials), [Analysis 1.9](#). No trial reported on the outcome cerebral palsy.

There was little evidence that monitoring by PR interval analysis conveyed any benefit.

DISCUSSION

Summary of main results

Overall, the ST waveform trials have shown some very modest benefits in terms of process indicators, with less obstetric interference (specifically, fetal blood sampling and operative vaginal delivery), but they have not shown substantive clinical benefits (e.g. reduced encephalopathy) among women allocated to ST waveform analysis in addition to standard cardiotocography

(CTG). The ST waveform trials used different generations of the same equipment (STAN recorder, Neoventa Medical, Gothenburg, Sweden). In the UK trial ([Westgate 1993](#)), the T/QRS ratio provided the basis for identifying ST segment elevation. In the subsequent trials ([Amer-Wahlin 2001](#); [Ojala 2006](#); [Vayssire 2007](#); [Westerhuis 2010](#); [Belfort 2015](#)), technical developments permitted the identification of ST waveform depression as well as elevation, since the former effect has also been seen in animal studies of experimentally-induced fetal hypoxaemia. Most trials were accompanied by regular education and training sessions for labour ward staff in both cardiotocogram and ECG waveform interpretation and these may be essential for optimal implementation.

Overall completeness and applicability of evidence

Identification of studies seems to be complete. All studies were performed in high-income settings.

Quality of the evidence

The trials were generally at low risk of bias for most 'Risk of bias' domains. The quality of evidence as assessed using the GRADE approach (see [GRADE handbook](#)) was graded moderate to high for ST waveform analysis trials (see [Summary of findings for the main comparison](#)). It was graded high for the following primary and secondary outcomes: caesarean section; neonatal encephalopathy; fetal blood sampling; operative vaginal delivery; admission to neonatal special care unit; and perinatal death. It was graded moderate for the following primary outcome: cord artery pH less than 7.05 and base deficit greater than 12 mmol/L. Downgrading for cord artery pH less than 7.05 and base deficit greater than 12 mmol/L was due to some heterogeneity in the findings.

Potential biases in the review process

A comprehensive search of the literature was conducted in order to minimise the possibility of publication bias. Only one review author assessed trials for inclusion and conducted data extraction and this is a potential bias of the review process. However, retrospective 'Risk of bias' assessments were conducted by more than one person (student medical statisticians) to minimise potential biases.

Agreements and disagreements with other studies or reviews

Five reported systematic reviews on this topic including four aggregate reviews (this Cochrane review included) and one individual patient data meta-analysis ([Schuit 2013](#)) have been critiqued by [Olofsson 2014](#).

AUTHORS' CONCLUSIONS

Implications for practice

ST waveform trials have shown a modest reduction in operative deliveries and fetal blood sampling, but they have not shown substantive clinical benefits, and there was a lack of evidence regarding PR interval analysis. These findings provide some very modest support for the use of fetal ST waveform analysis when a decision has been made to undertake continuous electronic fetal heart rate monitoring during labour. However, in most labours, technically satisfactory cardiotocographic traces can be obtained by external ultrasound monitors, which are less

invasive than internal scalp electrodes (which are required for electrocardiographic (ECG) analysis). The scalp electrode also cannot be used if the membranes are intact. One trial of fetal ECG analysis ([Amer-Wahlin 2001](#)) used guidelines for clinicians that recommended no action if cardiotocography (CTG) was normal, regardless of ST waveform analyses. This suggests that a better approach might be to consider using fetal ECG waveform analysis (of the ST waveform) only if CTG showed disquieting features.

Implications for research

The point estimates for effects of PR analysis are similar to those from the much larger ST studies, and the possibility of demonstrating beneficial effects from a larger PR trial could not be discounted. There is little information about the value of fetal ECG waveform monitoring in preterm fetuses in labour. Information about long-term development of the babies included in the trials would be valuable.

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REFERENCES

References to studies included in this review

Amer-Wahlin 2001 {published data only}

* Amer-Wahlin I, Hellsten C, Noren H, Hagberg H, Herbst A, Kjellmer I, et al. Cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram for intrapartum fetal monitoring: a Swedish randomised controlled trial. *Lancet* 2001;**358**:534-8.

Amer-Wahlin I, Kallen K, Herbst A, Rydhstroem H, Sundstrom AK, Marsal K. Implementation of new medical techniques: experience from the Swedish randomized controlled trial on fetal ecg during labor. *Journal of Maternal-Fetal & Neonatal Medicine* 2005;**18**(2):93-100.

Amer-Wahlin I, Kjellmer I, Marsal K, Olofsson P, Rosen KG. Swedish randomized controlled trial of cardiotocography versus cardiotocography plus ST analysis of fetal electrocardiogram revisited: analysis of data according to standard versus modified intention-to-treat principle. *Acta Obstetrica et Gynecologica Scandinavica* 2011;**90**(9):990-6.

Amer-Wahlin I, Marsal K, Noren H, Hellsten C. Randomized controlled trial of CTG versus CTG + ST analysis of the fetal ECG. XVI FIGO World Congress of Obstetrics and Gynecology (Book 3); 2000 Sept 3-8; Washington DC, USA. 2000:35.

Hagberg H, Amer-Wahlin I, Hellsten C, Noren H, Herbst A, Lilja H, et al. Intrapartum fetal monitoring: cardiotocography versus cardiotocography plus fetal ECG ST waveform analysis. A Swedish randomized controlled trial. *American Journal of Obstetrics and Gynecology* 2001;**184**(1):S19.

Hanson J. Cardiotocography and ST analysis for intrapartum fetal monitoring. *Lancet* 2011;**378**(9797):1137-8.

Lund University. Decision 16 September 2010.

Marsal K. Personal communication 7th January 2011.

Marsal K. Cardiotocography and ST analysis for intrapartum fetal monitoring - author's reply. *Lancet* 2011;**378**(9797):1138.

Noren H, Amer-Wahlin I, Hagberg H, Herbst A, Kjellmer I, Marsal K, et al. Fetal electrocardiography in labor and neonatal outcome: data from the Swedish randomized controlled trial on intrapartum fetal monitoring. *American Journal of Obstetrics and Gynecology* 2003;**188**(1):183-92.

Noren H, STAN study group. Randomised controlled trial of CTG versus CTG + ST analysis of the fetal ECG. *Prenatal and Neonatal Medicine* 2000;**5**(Suppl 2):37.

Sundstrom AK, Swedish STAN Group. Randomised controlled trial CTG versus CTG + ST analysis of the fetal ECG. *Journal of Obstetrics and Gynecology* 2001;**21**(Suppl 1):S18-S19.

Swedish Research Council. Opinion provided on request for investigation of suspected misconduct in research - the STAN study. Log no 312-2008-7602.

Belfort 2015 {published data only}

* Belfort MA, Saade GR, Thom E, Blackwell SC, Reddy UM, Thorp JM, et al. for the Eunice Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. A randomized trial of intrapartum fetal ECG ST-segment analysis. *New England Journal of Medicine* 2015;**373**:632-41.

Saade G, for Eunice Shriver NICHD Network. Fetal ECG analysis of the ST segment as an adjunct to intrapartum fetal heart rate monitoring: a randomized clinical trial. *American Journal of Obstetrics and Gynecology* 2015;**212**(1 Suppl 1):S2.

Ojala 2006 {published data only}

Ojala K, Vääräsmäki M, Mäkilallio K, Valkama M, Tekay A. A comparison of intrapartum automated fetal electrocardiography and conventional cardiotocography—a randomised controlled study. *BJOG: an international journal of obstetrics and gynaecology* 2006;**113**:419-23.

Strachan 2000 {published data only}

* Strachan BK, van Wijngaarden WJ, Sahota D, Chang A, James DK, for the FECG Study Group. Cardiotocography only versus cardiotocography plus PR-interval analysis in intrapartum surveillance: a randomised, multicentre trial. *Lancet* 2000;**355**:456-9.

van Wijngaarden WJ, Sahota DS, James DK, Farrell T, Mires GJ, Wilcox M, et al. Improved intrapartum surveillance with PR interval analysis of the fetal electrocardiogram: a randomised trial showing a reduction in fetal blood sampling. *American Journal of Obstetrics and Gynecology* 1996;**174**:1295-9.

van Wijngaarden WJ, Sahota DS, James DK, Symonds EM, Farrell T, Mires G. Does the fetal ECG improve intrapartum surveillance? II: A prospective evaluation. *International Journal of Gynecology & Obstetrics* 1994;**46**(Suppl 2):102.

Vayssiere 2007 {published data only}

Vayssiere C, David E, Haberstick R, Sebahoun V, Roth E, Meyer N, et al. A French randomized controlled trial on ST analysis in a population with abnormal FHR in labor. *American Journal of Obstetrics and Gynecology* 2006;**195**(6 Suppl 1):S222.

* Vayssiere C, David E, Meyer N, Haberstick R, Sebahoun V, Roth E, et al. A French randomized controlled trial of ST-segment analysis in a population with abnormal cardiotocograms during labor. *American Journal of Obstetrics and Gynecology* 2007;**197**(3):299.e1-e6.

Westerhuis 2010 {published data only}

Becker J, Westerhuis M, Sterrenburg K, Kwee A, Visser G. Fetal blood sampling in the Dutch STAN-trial: reason to adjust the clinical guidelines?. *American Journal of Obstetrics and Gynecology* 2009;**201**(6 Suppl 1):S240.

Becker JH, Westerhuis ME, Sterrenburg K, van den Akker ES, van Beek E, Bolte AC, et al. Fetal blood sampling in addition to intrapartum ST-analysis of the fetal electrocardiogram: evaluation of the recommendations in the Dutch STAN(R) trial.

BJOG: an international journal of obstetrics and gynaecology 2011;**118**(10):1239-46.

Kwee A. Cardiotocography plus ST-analysis of the fetal electrocardiogram versus cardiotocography only for intrapartum monitoring: a Dutch randomized trial. *Journal of Perinatal Medicine* 2009;**37**(Suppl 1):66.

Kwee A, Visser GHA. The cost-effectiveness of ST-analysis of the fetal electrocardiogram as compared to fetal blood sampling for intrapartum monitoring: a randomised controlled trial. Netherlands Trial Register (<http://www.trialregister.nl>) (accessed 1 November 2005).

Vijgen SMC, Westerhuis MEMH, Opmeer BC, Visser GHA, Moons KGM, Porath MM, et al. Cost-effectiveness of cardiotocography plus ST analysis of the fetal electrocardiogram compared with cardiotocography alone. *Acta Obstetrica et Gynecologica Scandinavica* 2011;**90**(7):772-8.

Westerhuis ME, Moons KG, van Beek E, Bijvoet SM, Drogtop AP, van Geijn HP, et al. A randomised clinical trial on cardiotocography plus fetal blood sampling versus cardiotocography plus ST-analysis of the fetal electrocardiogram (STAN) for intrapartum monitoring. *BMC Pregnancy and Childbirth* 2007;**7**:13.

* Westerhuis ME, Visser GH, Moons KG, van Beek E, Benders MJ, Bijvoet SM, et al. Cardiotocography plus ST analysis of fetal electrocardiogram compared with cardiotocography only for intrapartum monitoring: a randomized controlled trial. *Obstetrics & Gynecology* 2010;**115**(6):1173-80.

Westerhuis MEMH, Porath MM, Becker JH, Van Den Akker ESA, Van Beek E, Van Dessel HJHM, et al. Identification of cases with adverse neonatal outcome monitored by cardiotocography versus ST analysis: Secondary analysis of a randomized trial. *Acta Obstetrica et Gynecologica Scandinavica* 2012;**91**(7):830-7.

Westerhuis MEMH, Visser GHA, Moons KGM, Zuihthoff NPA, Mol BWJ, Kwee A. Cardiotocography plus ST analysis of fetal electrocardiogram compared with cardiotocography only for intrapartum monitoring: a randomized controlled trial. *Obstetrics & Gynecology* 2011;**117**:406-7; 412.

Westgate 1993 {published data only}

Westgate J, Harris M, Curnow J, Greene K. Plymouth randomised controlled trial of 2400 cases - ST waveform plus CTG vs CTG alone for intrapartum monitoring. Proceedings of 26th British Congress of Obstetrics and Gynaecology; 1992; Manchester, UK. 1992:177.

Westgate J, Harris M, Curnow JSH, Green KR. Randomized trial of cardiotocography alone or with ST waveform analysis for intrapartum monitoring. *Lancet* 1992;**340**:194-8.

Westgate J, Harris M, Curnow JSH, Greene KR. Plymouth randomized trial of CTG vs ST waveform analysis plus CTG for intrapartum monitoring: 2400 cases. *Journal of Perinatal Medicine* 1992;**20**(1):268.

* Westgate J, Harris M, Curnow JSH, Greene KR. Plymouth randomized trial of cardiotocogram only vs ST waveform plus cardiotocogram for intrapartum monitoring in 2400

cases. *American Journal of Obstetrics and Gynecology* 1993;**169**:1151-60.

References to studies excluded from this review

Hruban 2006 {published data only}

Hruban L, Janku P, Zahradnickova J, Kurecova B, Roztocil A, Kachlik P, et al. Role of ST-analysis of fetal ECG in intrapartum fetus monitoring with presumed growth retardation. *Ceska Gynekologie* 2006;**71**(4):268-72.

Ignatov 2012 {published data only}

Ignatov P, Atanasov B. [Indirect standard cardiotocography plus fetal blood sampling versus indirect quantitative cardiotocography--a randomized comparative study in intrapartum monitoring]. [Bulgarian]. *Akusherstvo i Ginekologiya* 2012;**51**(5):3-10.

Janku 2006 {published data only}

Janku P, Hruban L, Kurecova B, Roztocil A, Kachlik P, Zahradnickova J. ST analysis of fetal ECG in premature deliveries during 30th-36th week of pregnancy. *Ceska Gynekologie* 2006;**71**(3):163-8.

Olofsson 2003 {published data only}

Olofsson P. Current status of intrapartum fetal monitoring: cardiotocography versus cardiotocography + ST analysis of the fetal ECG. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2003;**110**:S113-S118.

Prieto 2008 {published data only}

Prieto AP, Pareja MV, Zuniga IV, Romero TA, Leon MDR, Ventoso FM. Pulse oximetry compared with fetal electrocardiogram to control intrapartum fetal wellbeing. *Journal of Maternal-Fetal and Neonatal Medicine* 2008;**21**(Suppl 1):141.

References to studies awaiting assessment

Gongora 2014 {published data only}

Gongora RJ, Naveiro SM, Ruiz DS, Puertas PA, Barranco AM, Carrillo BMP. A comparison of intrapartum fetal electrocardiography versus conventional cardiotocography in prolonged gestations: preliminary results. *Journal of Maternal-Fetal & Neonatal Medicine* 2014;**27**(Suppl 1):265.

References to ongoing studies

Bach 2012 {published data only}

Bach D, Secher NJ. Cardiotocography combined with ST-analysis versus cardiotocography combined with scalp-pH in deliveries with abnormal CTG - a randomised trial. ClinicalTrials.gov (<http://clinicaltrials.gov/>) [accessed 3 August 2014] 2012.

Spong 2013 {published data only}

Spong C. Fetal ST segment and T wave analysis in labor (STAN). ClinicalTrials.gov (<http://clinicaltrials.gov/>) 2010.

Additional references

Alfirevic 2013

Alfirevic Z, Devane D, Gyte GML. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. *Cochrane Database of Systematic Reviews* 2013, Issue 5. [DOI: [10.1002/14651858.CD006066](https://doi.org/10.1002/14651858.CD006066)]

Amer-Wahlin 2011

Amer-Wahlin I, Kjellmer I, Marsal K, Olofsson P, Rosen KG. Swedish randomized controlled trial of cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram revisited: Analysis of data according to standard versus modified intention-to-treat principle. *Acta Obstetrica et Gynecologica Scandinavica* 2011;**90**(9):990-6.

Dawes 1994

Dawes G, Meir YJ, Mandruzzato GP. Computerized evaluation of fetal heart rate patterns. *Journal of Perinatal Medicine* 1994;**22**:491-9.

Elbourne 2002

Elbourne DR, Altman DG, Higgins JPT, Curtin F, Vaillancourt JM. Meta-analyses involving cross-over trials: methodological issues. *International Journal of Epidemiology* 2002;**31**:140-9.

Greene 1987

Greene KG. The ECG waveform. In: Whittle M editor(s). *Bailliere's Clinical Obstetrics and Gynaecology*. Vol. **1**, London: Bailliere Tindall, 1987:131-55.

Greene 1999

Greene K. Intrapartum fetal monitoring: CTG, ECG and fetal blood sampling. In: Rodeck CH, Whittle MJ editor(s). *Fetal Medicine: Basic Science and Clinical Practice*. London: Churchill Livingstone, 1999:985-1004.

Higgins 2011

Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Marsal 2011

Marsal K. Cardiotocography and ST analysis for intrapartum fetal monitoring - author's reply. *Lancet* 2011;**378**(9797):1138.

Olofsson 2014

Olofsson P, Ayres-de-Campos D, Kessler J, Tendal B, Yli BM, Devoe L. A critical appraisal of the evidence for using cardiotocography plus ECG ST waveform analysis for fetal surveillance in labor. Part II: the meta-analyses. *Acta Obstetrica et Gynecologica Scandinavica* 2014;**93**:571-86.

RevMan 2014 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Rosen 1989

Rosen KG, Lindecrantz K. STAN - the Gothenburg model for fetal surveillance during labour by ST analysis of the fetal ECG. *Clinical Physics and Physiological Measurement* 1989;**10**(Suppl B):51-6.

Rosen 1991

Rosen KG, Arulkumaran S, Greene KR, Lilja H, Lindecrantz K, Seneviratne H, et al. Clinical validity of fetal ECG waveform analysis. In: Saling E editor(s). *Perinatology. Nutrition Workshop Series*. Vol. **26**, New York: Raven Press, 1991:95-110.

Schuit 2013

Schuit E, Amer-Wahlin I, Ojala K, Vayssire C, Westerhuis MEMH, Marsal K, et al. Effectiveness of electronic fetal monitoring with additional ST analysis in vertex singleton pregnancies beyond 36 weeks of gestation: an individual participant data meta-analysis. *American Journal of Obstetrics and Gynecology* 2013;**208**:187.e1-13.

Swedish Research Council 2010

Swedish Research Council. Opinion provided on request for investigation of suspected misconduct in research - the STAN study. Log no 312-2008-7602.

References to other published versions of this review

Neilson 1995

Neilson JP. Intrapartum fetal ECG plus heart rate recording. [revised 12 May 1994]. In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds) *Pregnancy and Childbirth Database* [database on disk and CDROM]. The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995.

Neilson 2003

Neilson JP Reviews. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *Cochrane Database of Systematic Reviews* 2003, Issue 2. [DOI: [10.1002/14651858.CD000116](https://doi.org/10.1002/14651858.CD000116)]

Neilson 2006

Neilson JP. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: [10.1002/14651858.CD000116.pub2](https://doi.org/10.1002/14651858.CD000116.pub2)]

Neilson 2012

Neilson JP. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *Cochrane Database of Systematic Reviews* 2012, Issue 4. [DOI: [10.1002/14651858.CD000116.pub3](https://doi.org/10.1002/14651858.CD000116.pub3)]

Neilson 2013

Neilson JP. Fetal electrocardiogram (ECG) for fetal monitoring during labour. *Cochrane Database of Systematic Reviews* 2013, Issue 5. [DOI: [10.1002/14651858.CD000116.pub4](https://doi.org/10.1002/14651858.CD000116.pub4)]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Amer-Wahlin 2001

Methods	Random allocation through computer-generated random numbers table, triggered by switching on the software in the fetal monitoring equipment.
Participants	4966 women in labour at > 36 weeks with singleton pregnancies, cephalic presentation and perceived need for continuous fetal heart rate monitoring via a fetal scalp electrode - high-risk pregnancies, suspicious or abnormal CTG, induced labour, oxytocin augmentation, meconium-stained amniotic fluid or epidural analgesia. The trial took place between 1998 and 2000 in 3 Swedish centres, Lund, Malmo, Gothenburg.
Interventions	CTG plus ST analysis of fetal ECG (2519 women) versus CTG alone (2477). The monitoring device was the STAN S21 (Neoventa Medical, Gothenburg), which incorporates an 'expert system' to provide advice to clinical staff. In this, it constitutes a technically more advanced system than used in the Westgate 1993 trial.
Outcomes	Primary: metabolic acidosis at birth (umbilical cord artery pH < 7.05 plus base deficit > 12 mmol/L). Secondary: operative deliveries, Apgar scores at 1 and 5 minutes, admissions to special care unit.
Notes	<p>Incomplete data available for acid-base results (2159 and 2079). The published report includes a secondary analysis performed after exclusion of babies with malformations and cases associated with trial protocol violations. The results included in this review are exclusively from the primary analysis, based on 'intention-to-treat'. An interim analysis was performed after around 1800 recruits; this revealed 'protocol violations' (failure to intervene on the basis of guidance in the research protocol) and the interim results were discussed with the clinical staff at the recruiting centres as part of a process of 're-training'. The study was co-funded by the Swedish Government Public Health Service, Neoventa Medical AB (manufacturer of the STAN device) and the Knowledge Foundation, Stockholm.</p> <p>Concerns were raised about the conduct and reporting of this trial, resulting in 3 separate external reviews. The final review (Swedish Research Council 2010) was critical of the role of the originator of the STAN device role as the monitor of trial - because of conflicted interests. The report also required the re-reporting of cord gas results (these have been corrected in the review and have now been published (Amer-Wahlin 2011; Marsal 2011)) but other reported outcomes were not in dispute. There was no suggestion of deliberate attempts to manipulate the data (University of Lund 2010).</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"the first number available from a computer-generated table of random numbers was used to assign the women [...] according to whether the number was even or odd." Pg 535 (Participants and methods – Methods).
Allocation concealment (selection bias)	Low risk	"Women were randomly assigned fetal monitoring [...] when STAN S21 equipment started up, the first number available from a computer-generated table of random numbers was used to assign the women [...] according to whether the number was even or odd." Pg 535 (Participants and methods – Methods).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Although no electrocardiographic information was available at the time of monitoring in the CTG group, fetal electrocardiogram signals were automatically stored for both groups for future analysis." Insufficient information.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"A paediatrician, who was unaware of which study group the neonate belonged to, assessed all paediatric files for babies admitted to the neonatal intensive-care unit, and judged whether there had been any signs of neonatal

Amer-Wahlin 2001 (Continued)

encephalopathy." This only applies to 1 of the secondary outcomes - there is insufficient information on the blinding of other outcomes assessed. Pg 536 (Participants and methods – Methods).		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data balanced in numbers across groups (283 from CTG group, 291 from CTG + ST group), with similar reasons for missing data across groups "574 cases excluded after the primary analysis.." "because of malformations or inadequate reading." Pg 536 (Figure 2), Pg 537 (Results).
Selective reporting (reporting bias)	Low risk	Study protocol not available but all of the study's expected (primary and secondary) outcomes that are of interest/pre-specified in the methods section have been reported in the results/tables, whether significant or not. "The rate of metabolic acidosis at birth was significantly lower in the CTG+ST group than in the CTG group. The number of operative deliveries for fetal distress was also significantly lower in the CTG + ST group. The rates of operative deliveries for other indications (in most cases failure to progress) did not differ significantly. Pg 536 (Results), Pg 537 (Table 3).
Other bias	Low risk	Appears to be free of other sources of bias.

Belfort 2015

Methods	Randomised trial.
Participants	11,108 women with singleton fetuses, > 36 weeks, attempting vaginal delivery, cervical dilatation 2-7 cms. Recruitment in one of 26 hospitals in network in USA, between November 2010 and March 2014. All hospitals had pilot experience of using ST-segment analysis equipment in at least 50 labours.
Interventions	The experimental group had results of fetal ECG ST-segment analysis revealed as adjunct to CTG findings; in the control group, the fetal ECG ST-segment analysis results were concealed ('masked').
Outcomes	Primary outcome: composite of intrapartum fetal death, neonatal death, Apgar score > 4 at 5 minutes, neonatal seizure, umbilical artery blood pH of 7.05 or less with base deficit of 12 mmol/L or more, intubation for ventilation at delivery, or neonatal encephalopathy. Maternal secondary outcomes: caesarean birth, assisted vaginal birth, chorioamnionitis, maternal blood transfusion, duration of labour, shoulder dystocia, postpartum endometritis, length of hospital stay. Neonatal secondary outcomes: components of primary outcome - Apgar score at 5 minutes, umbilical artery blood gas results, admission to intermediate care nursery or neonatal intensive care unit.
Notes	Intention to treat analysis. A 'protocol sub-committee' review of a sub-set of records in the revealed group found, retrospectively, that in some cases, management protocols were not followed correctly by clinical staff. Thus of 2427 women who were assigned to the open group and who had records assessed, 163 (6.7%) did not receive care according to STAN guidelines with 95 (3.9%) not receiving expedited delivery when recommended, and 68 (2.8%) having delivery expedited despite recommendation for continued observation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No explicit information about sequence generation.
Allocation concealment (selection bias)	Low risk	'Once a hospital was approved to participate in the randomized trial, the independent data coordinating center sent a software card containing the encrypted randomization module to the designated local biomedical technician to be

Belfort 2015 (Continued)

		installed on the S31 monitors at that hospital'. 'A separate randomization sequence was created for each monitor'.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible.
Blinding of outcome assessment (detection bias) All outcomes	High risk	A protocol sub-committee that was unaware of study group assignment conducted chart of review of all cases that met criteria for primary outcome.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full clinical data, and valid umbilical blood gas results obtained from 96.5% of neonates.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.
Other bias	Low risk	The study was supported by a government health research funder (NICHD) and by the manufacturer of the equipment (Neoventa). Neoventa had, it is stated, no role in monitoring the study, data collection and analysis, or manuscript preparation.

Ojala 2006

Methods	Opaque, consecutively numbered, sealed, envelopes containing randomisation code generated by computer programme in blocks of 100. Envelope opened at time of amniotomy.
Participants	1483 women randomised; 11 exclusions; clinical data available but blood gas data missing for 36. In labour at $\geq$ 36 weeks with singleton fetus, cephalic presentation, decision to perform amniotomy, no contraindication to scalp electrode. Sample size based on 50% reduction of umbilical artery pH $<$ 7.10.
Interventions	CTG plus ECG waveform analysis (STAN) (733 women) versus CTG (739 women). Fetal scalp sampling for pH estimation an option in either group. Recruitment in tertiary referral hospital in Finland 2003-4.
Outcomes	Neonatal acidemia, operative delivery, need for fetal scalp sampling for pH estimation.
Notes	In 83 pregnancies, there were technical difficulties in achieving satisfactory monitoring - n = 5 in CTG group; n = 78 in the ECG group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Opaque numbered sealed envelopes that contained a randomisation code generated by a computer program in blocks of 100." Pg 420 (Methods).
Allocation concealment (selection bias)	Low risk	"randomly assigned to two groups using opaque numbered sealed envelopes [...] This was arranged by a person independent of the study protocol. At the time of amniotomy, the next consecutively numbered envelope available was opened by a midwife not involved in the study." Pg 420 (Methods).
Blinding of participants and personnel (performance bias)	Unclear risk	"At the time of amniotomy, the next consecutively numbered envelope available was opened by a midwife not involved in the study." Insufficient information on blinding of participants.

Ojala 2006 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>“Eleven women were excluded from the outcome analysis [...] Umbilical artery blood gas analysis data were available for 1436” out of 1483 eligible.</p> <p>Missing blood gas analysis data balanced in numbers across groups (19 from STAN group, 17 from CTG group) with the same reasons across groups. Only missing data from 36/1472 participants. Pg 420 (Results), Pg 421 (Figure 1).</p>
Selective reporting (reporting bias)	Low risk	<p>Study protocol is not available but all of the study’s expected (primary and secondary) outcomes that are of interest/pre-specified in the methods section have been reported in the results/tables, whether significant or not.</p> <p>Pg 420 (Results), Pg 422 (Table 2), Pg 422 (Table 3).</p>
Other bias	Low risk	The study appears to be free of other sources of bias.

Strachan 2000

Methods	Random allocation through computer-generated random numbers table, triggered by switching on the software in the fetal monitoring equipment.
Participants	957 women in labour with perceived need for continuous fetal heart rate monitoring (age > 35, maternal disease, adverse obstetric history, prematurity, suspected fetal growth restriction, antepartum haemorrhage, breech presentation, multiple pregnancy, epidural analgesia, induction or augmentation of labour, abnormal CTG, meconium, previous caesarean section). Results are only available for 957 women (92%) for reasons that are unclear. The trial took place in 5 centres: Nottingham and Dundee (UK), Hong Kong, Amsterdam (The Netherlands) and Singapore.
Interventions	CTG plus fetal ECG (n = 482) versus CTG alone (n = 475).
Outcomes	The trial was powered to detect (alpha 80%, beta 5%) a decrease in 'unsuspected acidaemia' (cord artery pH < 7.15) from 8.5% to 4.5%.
Notes	The data monitoring committee recommended that the trial be stopped before recruitment of the target of 1192 for reasons that are not clear from the report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“Random number generation, as an integral part of the fetal ECG analyser program, was used to assign women to one of the two groups.” Pg 457 (Methods – Study design).
Allocation concealment (selection bias)	Unclear risk	“Random number generation [...] was used to assign women to one of the two groups.” Insufficient information on whether participants and enrolling investigators could foresee assignment. Pg 457 (Methods – Study design).
Blinding of participants and personnel (performance bias)	Unclear risk	<p>“In both groups, a conventional cardiotocography was available for interpretation by the labour-ward staff.”</p> <p>Insufficient information. Pg 457 (Methods – Study design).</p>

Fetal electrocardiogram (ECG) for fetal monitoring during labour (Review)

Strachan 2000 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	High risk	<p>“The signal was analysed with the Nottingham fetal ECG analyser; the relevant time-interval variables were displayed on-screen if the patient had been assigned to the cardiotocography plus fetal ECG group.”</p> <p>The relevant variables show on-screen for the intervention group, therefore the outcome assessor would know that if the variables are shown then that participant is in the intervention group. Pg 457 (Methods – Study design).</p>
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>“Delivery details were complete for 957 (92.2%)”.</p> <p>Of all women randomised into the trial “40 had incomplete delivery details” in both groups and 1 dropped out of the intervention group “because she didn't like the equipment in the room.” Missing outcome data balanced in numbers across both groups, but the reasons for missing data are not given, so there is insufficient information to make a judgement. Pg 457 (Flow chart of trial profile), Pg 458 (Results).</p>
Selective reporting (reporting bias)	Low risk	<p>Study protocol is not available but all the study's expected outcomes that are of interest/pre-specified in the methods section have been reported in the results/tables, whether significant or not. Pg 458 (Results, Table 2, Table 3, Table 4).</p>
Other bias	Unclear risk	<p>“Both problems with signal acquisition and failure to act on abnormal readings within the acidaemic group suggest that there may have been protocol violation within the trial group as a whole.” Pg 459 (Discussion).</p>

Vayssiere 2007

Methods	Sealed, numbered, opaque envelopes were prepared in a Research Unit. Details of randomisation are not described but there was stratification by centre (2). Allocation was by opening the next envelope.
Participants	799 women in labor at 36 weeks or more, with a single fetus with cephalic presentation, and either abnormal cardiotocographic trace or thick meconium-stained amniotic fluid. Exclusions included maternal infections that contraindicated scalp electrode attachment (e.g. HIV), cardiac malformation, severely abnormal CTG at the time of recruitment.
Interventions	CTG + fetal ECG (n = 399) versus CTG alone (n = 400). Scalp sampling for pH estimation was an option in both groups.
Outcomes	The trial was powered (alpha 5% beta 80%) to detect a reduction in operative deliveries for 'fetal distress' from 50% to 40%.
Notes	Fetal ECG was assessed by STAN S21 machines.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>“Envelopes for randomization, stratified by center, were prepared at the Delegation of Research Unit.”</p> <p>Insufficient information on how they achieved randomisation.</p>
Allocation concealment (selection bias)	Low risk	<p>“midwife who treated the women during labor opened an opaque numbered sealed envelope at randomization.” “Envelopes for randomization, stratified</p>

Fetal electrocardiogram (ECG) for fetal monitoring during labour (Review)

Vayssiere 2007 (Continued)

		by center, were prepared at the Delegation of Research Unit." Pg 299.e2 (Materials and methods).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"A research resident who was not involved in the study verified data during the study." Whilst unclear whether outcome assessors were blinded, the data were verified by someone independent of the study, therefore the outcome measurement is not likely to be influenced by lack of blinding. Pg 299.e2 (Materials and methods).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data – 799 women randomised after all exclusions (including 87 women who declined to participate) and were all included in the analysis. Pg 299.e3 (Results).
Selective reporting (reporting bias)	Low risk	Study protocol is not available but all of the study's expected (primary and secondary) outcomes that are of interest/pre-specified in the methods section have been reported in the results/tables, whether significant or not. Pg 299.e3 (Results, Table 2). Pg 299.e5 (Table 3).
Other bias	Unclear risk	Insufficient information.

Westerhuis 2010

Methods	A randomised clinical trial of CTG plus ST-analysis of the fetal ECG (STAN [®]) versus CTG alone for intrapartum fetal monitoring. Women randomised through a computer-generated randomisation sequence. Stratification for centre and parity (no previous vaginal delivery versus 1 or more previous vaginal deliveries). The study was performed in 9 hospitals in The Netherlands.	
Participants	5681 women in labour with a singleton fetus in vertex position, a gestational age 36 weeks or greater and a medical indication for electronic fetal monitoring. A medical indication is defined by either a high-risk pregnancy, induction or augmentation of labour, epidural anaesthesia, meconium-stained amniotic fluid or non-reassuring fetal heart rate.	
Interventions	Intervention group: CTG and ST-analysis. Control group: CTG.	
Outcomes	<p>Primary outcome: incidence of serious metabolic acidosis defined as a pH < 7.05 and a BDecf > 12 mmol/L in the umbilical cord artery.</p> <p>Secondary outcomes:</p> <ol style="list-style-type: none"> 1. incidence of serious metabolic acidosis defined as a pH < 7.05 and a BDblood > 12 mmol/L in the umbilical cord artery; 2. instrumental delivery rate because of fetal distress, failure to progress or a combination of the two; 3. neonatal outcome defined as Apgar scores < 4 after 1 minute and/or < 7 after 5 minutes; 4. need for admission to neonatal medium or intensive care unit; 5. incidence of performance of fetal blood sampling in both groups; 6. cost-effectiveness. 	
Notes		
Risk of bias		

Westerhuis 2010 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women "were randomized on a 1:1 basis through a web-based computer-generated randomization sequence with variable block size." Pg 1174 (Materials and methods).
Allocation concealment (selection bias)	Low risk	Web-based allocation. Women "were randomized on a 1:1 basis through a web-based computer-generated randomization sequence with variable block size." Pg 1174 (Materials and methods).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"As a result of the explicit pragmatic nature of the trial, both patients and care givers were not blinded to the allocated interventions" but the outcome is not likely to be influenced by a lack of blinding. Pg 1174 (Materials and methods).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Two neonatologists (F.G. and M.J.B.) who were blinded to randomization allocation independently assessed all neonatal admission letters and charts to evaluate whether signs of moderate or severe neonatal hypoxic-ischemic encephalopathy had developed according to Sarnat and Sarnat." Adequate blinding for the neonatal admissions. Pg 1175 (Materials and methods).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data – 5667 randomised to the trial (after 14 women excluded as they did not meet the inclusion criteria) and were included in the analysis - intention-to-treat analysis. "Various subjects had missing values. Because these are often selectively missing, which was also the case in our study [...] it is well documented that a complete case analysis likely yields biased results. Hence, we multiply imputed missing values (10 times) before doing the analysis, using the AregImpute method in S-plus." They have adopted an appropriate method for overcoming any impact, from missing values, on the risk of bias. Pg 1176 (Materials and methods). Pg 1176 (Materials and methods), Pg 1176 (Results, Fig. 1).
Selective reporting (reporting bias)	Low risk	Study protocol is not available but all of the study's expected (primary and secondary) outcomes that are of interest/pre-specified in the methods section have been reported in the results/tables, whether significant or not. Pg 1176 - 1177 (Results), Pg 1177 (Table 2), Pg 1178 (Table 3).
Other bias	Low risk	Appears to be free of other sources of bias.

Westgate 1993

Methods	Randomisation: entry to either group decided by draw of sealed, opaque envelopes once the decision to apply electrode was made. Trial preceded by randomised study to identify the best available scalp electrode for ECG recording - single spiral electrode, used in both groups of the study. On ST + CTG group the lead collection system also required a maternal thigh electrode be applied to standardise the ECG vector.
Participants	2434 pregnant women, 1215 CTG alone arm, 1219 ST waveform and CTG arm. (More than 34 weeks' gestation with no gross fetal abnormality.)

Westgate 1993 (Continued)

Interventions	CTG plus ST analysis (n =1219) versus CTG alone (n = 1215).
Outcomes	Obstetric intervention (fetal blood sampling and operative delivery) and fetal outcome.
Notes	Operative delivery rates separated into overall caesarean section rates and operative vaginal delivery rates not recorded in published report - information to be sought from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Entry to either arm was decided by draw of a sealed opaque envelope." Pg 1152 (Study entry and randomisation).
Allocation concealment (selection bias)	Low risk	"Entry to either arm was decided by draw of a sealed opaque envelope." Pg 1152 (Study entry and randomisation).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"All traces were reviewed blind to outcome by a single observer [...] in 30-minute segments without preview." Although not stated if blinded for other outcomes assessed, they are not likely to be influenced by the lack of blinding. Pg 1153 (Measurement of outcome – paragraph after Neonatal outcome).
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Three cases of noncompliance in the cardiotocogram arm. In two a recording was unobtainable [...] In the third there were no cardiotocogram recorders available." "There were 31 cases in the ST waveform plus cardiotocogram arm. Ten of these were protocol failure and four were technical failures [...] In 17 cases no satisfactory heart rate or electrocardiographic trace could be obtained.." An imbalance in numbers of missing data across the groups (3 from control, 31 from intervention), but overall only 34/2434 cases and the reasons for missing data are all unrelated to the true outcome. Pg 1154 (Results - Noncompliance with allocated recorder).
Selective reporting (reporting bias)	Unclear risk	Insufficient information.
Other bias	Low risk	Appears to be free of other sources of bias.

CTG: cardiotocography

ECG: electrocardiogram

ST + CTG: ST waveform and cardiotocogram

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Hruban 2006	Not randomised.
Ignatov 2012	Did not seem to involve analysis of fetal ECG waveform.

Study	Reason for exclusion
Janku 2006	Not randomised.
Olofsson 2003	Review article.
Prieto 2008	Randomised trial reported as abstract only, with insufficient detail to include data.

ECG: electrocardiogram

Characteristics of studies awaiting assessment *[ordered by study ID]*

[Gongora 2014](#)

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting publication of full report.

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

[Bach 2012](#)

Trial name or title	Cardiotocography combined with ST-analysis versus cardiotocography combined with scalp pH.
Methods	Randomised controlled trial.
Participants	Women > 18 years with fetus with cephalic presentation, > 36 + 0 weeks, in labour, undergoing CTG monitoring.
Interventions	CTG combined with ST-analysis versus cardiotocography combined with scalp pH.
Outcomes	Primary: metabolic acidosis at birth (umbilical artery pH < 7.05 base excess < -10).
Starting date	December 2005.
Contact information	Diana BB Bach.
Notes	Trial terminated for poor recruitment 2012. Unable to obtain data so far.

[Spong 2013](#)

Trial name or title	A randomised trial of fetal ECG ST segment and T wave analysis as an adjunct to electronic FHR monitoring (STAN).
Methods	Open-randomised trial.
Participants	Inclusion criteria:

Spong 2013 (Continued)

- Singleton, cephalic pregnancy
- Gestational age at least 36 weeks, 1 day
- Cervical dilation of at least 2 cm and no more than 7 cm
- Ruptured membranes

Interventions	Open group: FHR monitoring with ST analysis available. Masked group: FHR monitoring with ST analysis masked.
Outcomes	<ul style="list-style-type: none"> • Intrapartum fetal death • Neonatal death • Apgar score ≤ 3 at 5 minutes • Neonatal seizure • Cord artery pH ≤ 7.05 and base deficit ≥ 12 mmol/L • Intubation for ventilation at delivery • Presence of neonatal encephalopathy
Starting date	November 2010.
Contact information	Catherine C Spong spongc@mail.nih.gov
Notes	

CTG: cardiotocograph
ECG: electrocardiogram
FHR: fetal heart rate

DATA AND ANALYSES

Comparison 1. Fetal ECG plus CTG versus CTG alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 ST analysis	6	26446	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.96, 1.08]
1.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.61, 1.04]
2 Cord pH < 7.05 + base deficit > 12 mmol/L	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 ST analysis	6	25682	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.43, 1.20]
2.2 PR analysis	0	0	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Neonatal encephalopathy	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 ST analysis	6	26410	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.30, 1.22]
3.2 PR analysis	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Fetal blood sampling	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 ST analysis	4	9671	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.41, 0.91]
4.2 PR analysis	1	957	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.69, 1.19]
5 Operative vaginal delivery	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 ST analysis	6	26446	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.86, 0.99]
5.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.75, 1.17]
6 Apgar score < 7 at 5 minutes	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 ST analysis	5	15302	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.73, 1.24]
6.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.11, 1.62]
7 Neonatal intubation	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 ST analysis	2	12544	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.89, 2.11]
7.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.26, 2.11]
8 Admission neonatal special care unit	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 ST analysis	6	26410	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.89, 1.04]
8.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.45, 1.33]
9 Perinatal death	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.1 ST analysis	6	26446	Risk Ratio (M-H, Fixed, 95% CI)	1.71 [0.67, 4.33]
9.2 PR analysis	1	957	Risk Ratio (M-H, Fixed, 95% CI)	2.96 [0.12, 72.39]

Analysis 1.1. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 1 Caesarean section.

Analysis 1.2. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 2 Cord pH < 7.05 + base deficit > 12 mmol/L.

Analysis 1.3. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 3 Neonatal encephalopathy.

Analysis 1.4. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 4 Fetal blood sampling.

Analysis 1.5. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 5 Operative vaginal delivery.

Analysis 1.6. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 6 Apgar score < 7 at 5 minutes.

Analysis 1.7. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 7 Neonatal intubation.

Analysis 1.8. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 8 Admission neonatal special care unit.

Analysis 1.9. Comparison 1 Fetal ECG plus CTG versus CTG alone, Outcome 9 Perinatal death.

WHAT'S NEW

Date	Event	Description
23 September 2015	New search has been performed	Search updated. Five new reports identified (four trials): one was included (Belfort 2015); one was excluded (Ignatov 2012); one is awaiting classification (Gongora 2014); and one is ongoing (Bach 2012). 'Risk of bias' tables completed with retrospective information.
23 September 2015	New citation required but conclusions have not changed	Conclusions remain unchanged. A 'Summary of findings' table has been incorporated.

HISTORY

Protocol first published: Issue 2, 1997

Review first published: Issue 2, 1997

Date	Event	Description
12 March 2013	New citation required but conclusions have not changed	Review updated.
12 February 2013	New search has been performed	New search. No new trials identified but citation for a secondary analysis of data from Westerhuis 2010 trial added, and ongoing trial in US noted (Spong 2013).
28 February 2012	New citation required but conclusions have not changed	Review updated.
28 February 2012	New search has been performed	Search updated. No new trials identified. References are included to published revisions of the Amer-Wahlin 2001 trial data. Economic analysis of the Westerhuis 2010 trial data cited.
19 May 2011	New search has been performed	Search updated. New trial added (Westerhuis 2010). Results of existing trial (Amer-Wahlin 2001) modified, with explanation. Outcome measures refined and classed as primary and secondary. Although the results are different, the overall conclusions remain unchanged.

Date	Event	Description
17 April 2009	New search has been performed	Search updated and two excluded studies added (Hruban 2006 ; Janku 2006). Unpublished data from the Vayssiere 2007 trial added.
10 November 2008	New search has been performed	The search has been updated and an additional trial added (Vayssiere 2007).
4 November 2008	Amended	It came to our notice that one of the included trials was being investigated by the relevant university because of allegations of research misconduct. We have added text to the review to advise that the results of this review should be interpreted with great caution until the university investigation is completed and the conclusions publicised.
2 September 2008	Amended	Converted to new review format.
6 April 2006	New search has been performed	Search updated. Data from a newly published trial from Finland have been included. A recent publication has discussed the identification of 'protocol violations' at interim analysis mid-way through the Swedish trial; these were used to 're-train' clinical staff in the recruiting centres.

CONTRIBUTIONS OF AUTHORS

JP Neilson has prepared and maintained the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- The University of Liverpool, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Methods updated. A 'Summary of findings' table has been added.

INDEX TERMS

Medical Subject Headings (MeSH)

*Labor, Obstetric; Acidosis [epidemiology]; Cardiotocography [*methods]; Cesarean Section [statistics & numerical data]; Electrocardiography [*methods]; Heart Rate, Fetal [*physiology]; Randomized Controlled Trials as Topic; Uterine Contraction [physiology]

MeSH check words

Female; Humans; Pregnancy