ISRCTN98680152 https://doi.org/10.1186/ISRCTN98680152

# A multicentre randomised controlled trial of an intelligent system to support decision making in the management of labour using the cardiotocogram

**Submission date**
25/09/2008

**Recruitment status**
No longer recruiting

**Registration date**
30/09/2008

**Overall study status**
Completed

**Last Edited**
18/08/2020

**Condition category**
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Babies continue to die in labour or are born with brain injury due to a lack of oxygen during their birth. One way of trying to prevent babies suffering due to a lack of oxygen during birth is to monitor the baby's heart rate. This monitoring is not always easy to interpret. Some patterns are the baby's normal response to the stress of labour whilst others indicate a lack of oxygen. Expertise and experience are essential for accurate interpretation, and mistakes are common. This study will test whether an intelligent computer program can help midwives and doctors improve the care they give in response to abnormalities of the baby's heart rate, and whether this will lead to fewer babies being harmed because of a lack of oxygen.

Who can participate?
Pregnant women who require electronic foetal monitoring (EFM)

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives standard care, with the healthcare team looking at the readings from the monitor. In the other group the monitoring is looked at by the 'intelligent' computer system as well as the healthcare team. Information is collected during labour on a monitoring machine. We also record details of when the mother and baby are discharged from the hospital, and details of any treatments they receive whilst in hospital. Some of the participants are also contacted with questionnaires at 1 and 2 years after the birth to ask about their general health and how often they have used the NHS since giving birth.

What are the possible benefits and risks of participating?
We cannot promise that the study will help participants but the information we get from this study may help improve the care provided to women in labour in the future. All information we collect will be kept strictly confidential. Participant will still receive the same level of monitoring from the doctors and midwife whether you participate in the study or not.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2009 to May 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. Peter Brocklehurst

# Contact information

### Type(s)
Scientific

### Contact name
Prof Peter Brocklehurst

### Contact details
National Perinatal Epidemiology Unit (NPEU)
University of Oxford
Old Road Campus
Oxford
United Kingdom
OX3 7LF

# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT02010710

### Protocol serial number
HTA 06/38/01

# Study information

### Scientific Title
A multicentre randomised controlled trial of an intelligent system to support decision making in the management of labour using the cardiotocogram (INFANT)

### Acronym
INFANT (INtelligent Foetal AssessmeNT)

### Study objectives
The study will test whether use of decision-support software can help midwives and doctors improve the care they give in response to abnormalities of the baby's heart rate during labour and whether this will lead to fewer babies being harmed because of a lack of oxygen.

The objectives of the study are:
1. To determine whether intelligent decision-support can improve interpretation of the intrapartum cardiotocograph (CTG) and therefore improve the management of labour for women who are judged to require continuous electronic heart rate monitoring. Specifically, will the system, compared with current clinical practice:
1.1. Identify more clinically significant heart rate abnormalities?
1.2. Result in more prompt and timely action on clinically significant heart rate abnormalities?
1.3. Result in fewer "poor neonatal outcomes"?
1.4. Change the incidence of operative interventions?
2. To assess whether use of intelligent decision-support improves the quality of routine care received by women undergoing continuous electronic fetal monitoring during labour. This information will be important for evaluating whether the decision-support software decreases the risk of suboptimal care in labour; it will also be useful to explore the effect that such an intervention may have on litigation for obstetrics.
3. To determine whether the use of the decision-support software is cost-effective in terms of the incremental cost per poor perinatal outcome prevented.
4. To determine whether use of the decision-support software has any effect on the longer term neurodevelopment of children born to women participating in the INFANT study

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/063801
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/51383/PRO-06-38-01.pdf

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Northern & Yorkshire Research Ethics Committee (REC), ref: 09/H0903/31

## Study design
Multicentre randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Labour management

## Interventions
The specific piece of decision-support software to be evaluated in INFANT has been designed by K2 Medical Systems to run on the K2 data collection system (Guardian™). The data collection system Guardian™ is a system for managing information from labour monitoring. It displays the CTG on a computer screen alongside other clinical data which are collected as part of routine clinical care.

The decision-support software being evaluated in INFANT extracts the important features of baseline heart rate, heart-rate variability, accelerations, type and timing of decelerations, the quality of the signal and the contraction pattern from the CTG. The decision-support software

then analyses these data along with the quality of the signals. The system's assessment of the CTG is presented as a series of alerts or alarms depending on the severity of the abnormality detected. The clinician is able to review the system's logical reasoning by selecting a 'why' button. The system can therefore be viewed as an intelligent prompt, but by recording the chronology of events it also offers the opportunity to later audit the actual clinical decision-making process.

The Guardian™ system on each labour ward will include random-number-generation software which will assign participating women to 'no decision-support' or 'decision-support'. Clinicians will not be masked to allocation. The aim is to randomise 46,000 women to the trial over 36 months.

A random sample of 7,000 surviving children (3,500 in each group) will be followed up at two years of age. This sample will be taken from within the sample recruited during the first two years of the project so that follow-up of this group can be completed around the time that the trial stops recruiting.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
1. Short term: 'Poor neonatal outcome' to include:
1.1. All perinatal deaths, except deaths due to congenital anomalies
1.2. Significant morbidity: neonatal encephalopathy; other admissions to neonatal intensive care unit (NICU) within 48 hours of birth for 48 hours or more, which are associated with adverse intrapartum events including respiratory symptoms and seizures
2. Long term: Developmental Quotient (DQ) at the age of two years

### Key secondary outcome(s))
1. Cord-artery pH <7.05 with base deficit of 12 mmol/l or more
2. Apgar score <4 at 5 minutes
3. Caesarean section
4. Any operative intervention for (i) foetal distress and (ii) failure to progress
5. Foetal blood sampling
6. Length of labour
7. Episiotomy rates
8. Proportion of babies with an adverse outcome (trial primary outcome plus cord-artery pH <7.05 with base deficit 12 mmol/l or more) judged to have experienced suboptimal care in labour

### Completion date
31/05/2014

## Eligibility

### Key inclusion criteria
Women admitted to a participating labour ward who fulfil all of the following criteria will be eligible to be randomised in the trial (no age limits):
1. They are judged to require continuous electronic foetal monitoring (EFM) by the local clinical

team based on their existing guidelines, and the woman consents to have EFM, and EFM is possible
2. They have a singleton or twin pregnancy
3. They are above or equal to 35 weeks' gestation
4. There is no known gross foetal abnormality
5. They are able to give consent to participate in the trial as judged by the attending clinicians

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Triplets or higher order pregnancy
2. Criteria for EFM not met

### Date of first enrolment
01/09/2009

### Date of final enrolment
31/05/2014

## Locations

### Countries of recruitment
United Kingdom

England

Ireland

### Study participating centre
**University of Oxford**
Oxford
United Kingdom
OX3 7LF

## Sponsor information

**Organisation**
University of Oxford (UK)

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 29/04/2017 | | Yes | No |
| Results article | results | 01/02/2018 | | Yes | No |
| Protocol article | protocol | 20/01/2016 | | Yes | No |
| Other publications | economic evaluation | 01/03/2021 | 18/08/2020 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |