ISRCTN46449237 https://doi.org/10.1186/ISRCTN46449237

A randomised trial to determine whether CTG monitoring with a computerised decision aide can improve pregnancy outcomes

Submission date
08/09/2014

Recruitment status
No longer recruiting

Registration date
02/10/2014

Overall study status
Completed

Last Edited
30/08/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A cardiotocography (CTG) machine is used during labour to monitor both the baby's heart rate and the mothers contractions while the baby is still in the womb. Doctors and midwives use this information to see how the baby is doing and to help them in deciding what action to take should problems occur. However, CTG data can be difficult to understand, which can mean that the best decisions are not always made. Computerised decision aides that improve the understanding of CTG data may help to prevent such poor decisions. This study is an early phase trial to see whether a computerised decision aide can improve the chances of a safe and successful delivery among women who were monitored using a CTG with an aide compared to women who were monitored using CTG alone.

Who can participate?
Women aged over 18 who are pregnant with one baby. Upon admission to the labour ward, the baby should be in cephalic position (head down) and have no structural abnormalities.

What does the study involve?
Upon admission to the labour ward, each participant is randomly allocated into one of two groups. Those in the treatment group are monitored with a CTG connected to a computerised decision support aide. Those in the control group receive standard care (i.e. a CTG machine with no computerised decision support aide). Obstetric data is collected regarding the delivery for the study.

What are the possible benefits and risks of participating?
Since the decision aide is designed to help clinical decision making, possible benefits of participating in the study include a reduced risk of an infant experiencing a shortage of oxygen (hypoxia) and unnecessary Caesarean delivery. Women not given the treatment will receive standard care according to hospital protocol. Thus, given the non-invasive nature of the decision aide the likelihood of risks are very small.

Where is the study run from?
The Second Municipal Hospital for Obstetrics and Gynecology Sheynovo, Sofia (Bulgaria)

When is the study starting and how long is it expected to run?
March 2008 to March 2011

Who is funding the study?
1. Bulgarian Christmas 2013-2014 Charity Initiative (Bulgaria)
2. Sheynovo - Second Municipal Hospital for Obstetrics and Gynaecology (Bulgaria)

Who is the main contact?
Dr. Peter Ignatov
ignatov@orthogyn.com

Contact information

Type(s)
Scientific

Contact name
Dr Peter Ignatov

Contact details
41-43 Skobelev bul.
Sofia
Bulgaria
1606

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Indirect quantitative cardiotocography (qCTG) versus indirect standard cardiography plus fetal blood sampling (CTG+FBS) - a randomised comparative study in intrapartum monitoring

Study objectives
We hypothesise that the incidence of hypoxia, acidaemia and operative delivery due to foetal distress will be reduced in women monitored with a cardiotocography (CTG) machine with a

decision aide versus women monitored with CTG alone. The null hypothesis is that there will be no difference between treatment groups. A null association may occur if the decision aide does not adequately discriminate between normal and abnormal CTG traces.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Second Municipal Hospital for Obstetrics and Gynecology Sheynovo, Sofia, Bulgaria, 19/02/2008, ref. 00134/19.02.2008

Study design
Randomised control trial 1:1 computer-generated randomisation sequence; permuted blocks with randomly varied block sizes (10, 20)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
CTG monitoring with a decision aide to reduce Caesarean delivery

Interventions
Participants are randomly allocated to one of two groups:
1. Intervention group receive CTG with an a decision aide
2. Control group receive CTG only (and fetal blood sampling, if necessary)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Occurrence of hypoxia (pH <7.20)
2. Occurrence of acidaemia (pH <7.05)
3. Caesarean delivery
4. Forceps extraction

Secondary outcome measures
1. Apgar score <7 at 5 minutes
2. Neonatal seizures
3. Admission to NICU

All outcomes are immediately after birth with the exception of neonatal seizures and NICU admission. Neonatal seizures and NICU admission are within the first 24 hours after delivery

Overall study start date
14/03/2008

Completion date
14/03/2011

Eligibility

Key inclusion criteria
Women admitted to labour ward who:
1. Were aged 18 years and older
2. Had a singleton pregnancy
3. Had an baby in cephalic position
4. Presented with no ultrasound/laboratory evidence of structural abnormalities of the baby

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
720

Key exclusion criteria
Women admitted to labour ward who:
1. Were aged <18 years
2. Had multiple gestations
3. Had a baby with an abnormal lie
4. Had a baby with known structural abnormalities as confirmed through ultrasound of laboratory testing

Date of first enrolment
14/03/2008

Date of final enrolment

14/03/2011

Locations

Countries of recruitment
Bulgaria

Study participating centre
41-43 Skobelev bul.
Sofia
Bulgaria
1606

Sponsor information

Organisation
Second Municipal Hospital for Obstetrics and Gynaecology Sheynovo / Bulgarian Christmas 2007-2011 Charity Initiative (Bulgaria)

Sponsor details
19 Sheynovo str. / 2 Dondukov str.
Sofia
Bulgaria
1504 / 1123

Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Bulgarian Christmas 2013-2014 Charity Initiative (Bulgaria)

Funder Name
Sheynovo - Second Municipal Hospital for Obstetrics and Gynaecology (Bulgaria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016		Yes	No