

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

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Registration date 02/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

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

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