

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

<b>Submission date</b> 08/09/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/08/2016	<b>Condition category</b> Pregnancy and Childbirth	<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

Dr Peter Ignatov

### Contact details

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## Additional identifiers

## 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?
<a href="#">Results article</a>	results	01/10/2016		Yes	No