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Comparing second-line tests in labour to assess fetal well-being

Submission date
25/02/2018

Recruitment status
Suspended

Registration date
27/07/2018

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Continuous electronic fetal heart rate recording with cardiotocography (CTG) is a standard approach to monitor fetal wellbeing in labour and is recommended for high-risk pregnancies. The aim is to identify fetal compromise early and intervene in order to reduce serious adverse events such as brain damage and death of a baby. CTG abnormalities are relatively common and can lead to the decision to deliver by emergency caesarean section. In most cases the fetus is subsequently found to have been compensating for the stress of labour and is not actually compromised. Fetal blood sampling (FBS) is a second-line invasive test that provides information on hypoxia (low oxygen levels). It is used to provide either reassurance that labour can continue, or more objective evidence that delivery needs to happen sooner. Clinical guidelines in the UK and Ireland treat FBS as a gold standard test. Recent studies have questioned the validity and reliability of FBS, and also the logistic challenges of achieving a result in a timely manner. Fetal scalp stimulation (FSS) is an alternative non-invasive test of fetal wellbeing in labour and is recommended in preference to FBS in North American guidelines. This study aims to compare FSS and FBS in women with term single pregnancies and an abnormal labour CTG, where additional information on fetal wellbeing is required.

Who can participate?
Women with a single pregnancy (gestational age over 36 weeks) with an abnormal CTG that requires further assessment by fetal blood sampling

What does the study involve?
Participants are randomly allocated to receive either standard care (FBS) or FSS. Women allocated to receive standard care are managed according to Royal College of Obstetricians and Gynaecologists (RCOG) guidelines and the local hospital protocol. The women are assessed by abdominal and digital vaginal examination before fetal blood sampling. Once the decision to perform a fetal blood sample has been made, fetal capillary blood samples are collected and analysed in the delivery suite. The result of the first technically reliable sample is interpreted and acted upon according to the protocol, taking account of the clinical circumstances and the stage of labour. Women in the FSS group are managed in the same way except FSS is performed instead of FBS. An abdominal and vaginal assessment is performed as usual. The examiner stimulates the fetal scalp digitally with the index finger over a period of 30 seconds. The CTG is

observed over a 5 to 10 minute interval after the FSS and if fetal heart rate acceleration and good fetal heart rate variability is observed the FSS test is considered normal (reassuring) and should be interpreted in the same way as a normal pH result following FBS. If there is no fetal rate acceleration and no episode of good variability the FSS should be interpreted as abnormal in the same way as an abnormal FBS result and warrants expedited delivery in keeping with the clinical circumstances, or an FBS can be performed. If there is uncertainty whether the criteria for a normal FSS have been fully met it can be repeated in 30 minutes. Rates of caesarean section are compared between the two groups.

What are the possible benefits and risks of participating?
The benefit of participating for those allocated to FSS is that it may reduce the number of invasive procedures and reduce the number of caesarean sections. However, to ensure the safety of every participant decision making is at the discretion of the responsible clinician and if there are clinical concerns this should override the study. In all cases of either FBS or FSS the results need to be interpreted as part of the full clinical picture. If the result seems completely out of keeping with the full clinical picture this needs to be discussed with the Consultant Obstetrician.

Where is the study run from?
1. Coombe Women & Infants University Hospital (Ireland)
2. Rotunda Hospital (Ireland)
3. Cork University Maternity Hospital (Ireland)
4. Limerick University Maternity Hospital (Ireland)
5. Royal Jubilee Hospital Belfast (UK)

When is the study starting and how long is it expected to run for?
August 2016 to June 2021

Who is funding the study?
Trinity College Dublin (Ireland)

Who is the main contact?
Prof. Deirdre Murphy
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Contact information

Type(s)
Scientific

Contact name
Prof Deirdre Murphy

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1 30.06.16

Study information

Scientific Title
Fetal Scalp Stimulation (FSS) versus Fetal Blood Sampling (FBS) to assess fetal well-being in labour - a multi-centre randomised controlled trial

Study objectives
The hypothesis for the study is that digital fetal scalp stimulation (dFSS) performs better than fetal blood sampling (FBS) in terms of correctly identifying or excluding fetal acidosis and that it reduces the rate of emergency caesarean section in labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coombe Women & Infants University Hospital REC, 11/05/2017, Study No. 10-2017

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Fetal well-being in labour

Interventions
Allocation of eligible women who consent to participate in the trial will be concealed using a fully automated centralised web-based system provided by the Nottingham Randomised Trials Collaboration. The randomisation sequence will be created by using block sizes of 4, 8 and 12 and stratified by centre in a 1:1 ratio for standard care versus intervention.

Standard care arm (FBS)
Women allocated to receive standard care will be managed according to Royal College of Obstetricians and Gynaecologists (RCOG) guidelines and the local hospital protocol. The women will be assessed by abdominal and digital vaginal examination prior to fetal blood sampling. Once the decision to perform a fetal blood sample has been made, fetal capillary blood samples will be collected in heparinised glass tubes and analysed in the delivery suite using the locally available gas analyser. The result of the first technically reliable sample will be interpreted and acted upon according to the protocol, taking account of the clinical circumstances and the stage of labour.

Intervention arm (dFSS)
Women in the intervention group will be managed in the same way except dFSS will be performed instead of FBS. An abdominal and vaginal assessment will be performed as usual. The examiner will stimulate the fetal scalp digitally with the index finger over a period of 30 seconds. The woman will be optimally positioned avoiding aorto-caval compression (tilted towards the left lateral). The CTG will be observed over a 5 to 10 minute interval after the FSS and if a fetal heart rate acceleration (15 15 bpm for 15 seconds) and an episode of good fetal heart rate variability (≥10 bpm) is observed the FSS test will be considered normal (reassuring) and should be interpreted in the same way as a normal pH result following FBS. If there is no fetal rate acceleration and no episode of good variability the FSS should be interpreted as abnormal in the same way as an abnormal FBS result and warrants expedited delivery in keeping with the clinical circumstances or an FBS can be performed. If there is uncertainty whether the criteria for a normal FSS have been fully met it can be repeated in 30 minutes as with a borderline pH result.

Intervention Type
Other

Primary outcome measure
Incidence of caesarean section in labour, recorded from the computerised records prior to hospital discharge

Secondary outcome measures
All outcomes recorded from computerised records prior to hospital discharge:
1. Incidence of caesarean section by primary indication (maternal/fetal)
2. Incidence of operative vaginal delivery
3. Incidence of low Apgar scores (<7 at 5 minutes), fetal acidosis (pH artery <7.10 or base excess <-12.0), admission to the neonatal unit, neonatal encephalopathy requiring therapeutic hypothermia
4. Incidence of primary postpartum haemorrhage (>500ml), major obstetric haemorrhage (>1000ml), third and fourth degree perineal tears (OASI), admission to High Dependency Unit (HDU)
5. Prolonged postnatal admission (> 5 days)
6. Number of second-line tests performed, number of FBS procedures and attendances of medical staff to review the CTG

Overall study start date
01/08/2016

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Women with a singleton pregnancy
2. Cephalic presentation
3. Gestational age greater than 36 weeks
4. Abnormal CTG that requires further assessment by fetal blood sampling

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3000

Key exclusion criteria
1. Women with a contraindication to FBS
2. Limited understanding of English
3. Under 18 years of age
4. Eligibility will also be at the discretion of the responsible obstetrician in cases where there is urgency due to suspected fetal compromise (“fetal distress”)

Date of first enrolment
01/02/2019

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
Ireland

Northern Ireland

United Kingdom

Study participating centre
Coombe Women & Infants University Hospital
Cork St
Dublin
Ireland
D08 XW7X

Study participating centre
Rotunda Hospital
Dublin
Ireland
DO1 P5W9

Study participating centre
Cork University Maternity Hospital
Wilton
Cork
Ireland
-

Study participating centre
Limerick University Maternity Hospital
Limerick
Ireland
V94 C566

Study participating centre
Royal Jubilee Hospital Belfast
Belfast
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BT12 6BA

Sponsor information

Organisation
Trinity College Dublin

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
University/education

Funder Name
Trinity College Dublin

Alternative Name(s)
Coláiste na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Publication and dissemination plan
The aim is to raise awareness of this clinical question and the proposed research approach at local, national and international meetings. The trialists plan to publish the study protocol with a statistical analysis plan. A final report will be prepared for the funding body and papers will be prepared for peer-review publication and national/international dissemination. The trialists will include the trial results in an updated edition of the Cochrane review that they are leading. They will liaise with national and International guideline developers (RCOG/NICE/ACOG/SOGC) to ensure that the trial findings are incorporated into evidence-based practice guidelines and reach the target audience as early as possible.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Deirdre Murphy (murphyd4@tcd.ie).

IPD sharing plan summary
Available on request