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Ultrasound assessment of the fetal head position to prevent morbidity at instrumental delivery

Submission date
19/01/2011

Recruitment status
No longer recruiting

Registration date
23/02/2011

Overall study status
Completed

Last Edited
18/02/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multi-centre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery

Acronym
IDUS - Instrumental Delivery and UltraSound

Study objectives
The hypothesis is that an abdominal ultrasound scan performed in addition to routine clinical assessment reduces the incidence of incorrect diagnosis of the fetal head position which will reduce the risk of maternal and perinatal morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Granted by the Research Ethics Committee of the Coombe Women & Infants University Hospital Dublin on the 5th October 2010

Study design
Multicentre individually randomised parallel two-arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Fetal head position in labour

Interventions
Eligible women who have consented to participate in the trial will be allocated to either the usual care arm or intervention arm. Women allocated to receive usual care will be managed according to RCOG guidelines and the local hospital protocol.

Women in the intervention group will be managed in the same way. In addition they will receive an ultrasound scan to assess the position of the fetal head and spine.

In both groups, the mother and the neonate will be followed-up until hospital discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incorrect diagnosis of the fetal head position

Secondary outcome measures
Secondary neonatal outcomes will include trauma, low Apgar scores, low arterial blood gases and admission to the neonatal intensive care unit (NICU). Neonatal trauma will include bruising, laceration, cephalhaematoma, retinal haemorrhage, facial nerve palsy, brachial plexus injury and fractures. Paired cord blood gases will be taken routinely to measure arterial and venous pH and base excess. Arterial pH below 7.10 and base excess greater than -12.0 mmol/l will be used as the threshold to define significant fetal acidosis.

Secondary maternal outcomes will include extensive perineal tearing involving the anal sphincter (third or fourth degree tears), postpartum haemorrhage, shoulder dystocia, and length of postnatal hospital stay. Primary post partum haemorrhage is defined as an estimated blood loss at delivery and in the first 24 hours of more than 500mls. Postnatal stay will be considered prolonged if more than 3 days' duration. Maternal and neonatal complications will be defined clinically according to the attending clinicians.

Overall study start date
10/01/2011

Completion date
30/11/2013

Eligibility

Key inclusion criteria
The study will be limited to nulliparous women at term with singleton cephalic pregnancies, aiming to deliver vaginally who require an instrumental delivery in the second stage of labour.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
450

Key exclusion criteria
Women with a contraindication to instrumental delivery, or who have a limited understanding of English or are under 18 years of age.

Date of first enrolment
10/01/2011

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
Ireland

Study participating centre
The Coombe Women and Infants University Hospital
Dublin
Ireland
D8

Sponsor information

Organisation
The Coombe Women and Infants University Hospital (Ireland)

Sponsor details
The Coombe
Dublin
Ireland
D8

Sponsor type
Hospital/treatment centre

Website
http://www.tcd.ie/

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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?
Protocol article	protocol	13/09/2012		Yes	No
Results article	nested observational study results	01/03/2015	18/02/2021	Yes	No