

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

Submission date 19/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Screening

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(s)

Incorrect diagnosis of the fetal head position

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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