

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Meenakshi Ramphul

### Contact details

The Coombe Women and Infants University Hospital

The Coombe

Dublin

Ireland

D8

## 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? |
|--|------------------------------------|--------------|------------|----------------|-----------------|
| <a href="#"><u>Results article</u></a>               | nested observational study results | 01/03/2015   | 18/02/2021 | Yes            | No              |
| <a href="#"><u>Protocol article</u></a>              | protocol                           | 13/09/2012   |            | Yes            | No              |
| <a href="#"><u>Participant information sheet</u></a> | Participant information sheet      | 11/11/2025   | 11/11/2025 | No             | Yes             |