

# A trial of manual versus instrumental rotation of malpositioned babies at birth

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| <b>Submission date</b><br>26/10/2022   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>24/11/2022 | <b>Overall study status</b><br>Completed              | <input checked="" type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>29/05/2025       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Making birth safer to prevent poor outcomes for mothers and their babies is an NHS priority. We know that births complicated by assisted birth can cause long-term health problems for women which can affect their physical and emotional health, relationships and careers. It can also have serious consequences for the baby. An assisted vaginal birth often happens when the baby is awkwardly positioned in the birth canal, for example when the baby's spine is resting against the mother's spine. This makes it much harder for the mother to push her baby out. Around 30,000 women per year in the UK (one in 25) are affected. In these cases doctors (obstetricians) and midwives will try to turn the baby into a better position, using either instruments (forceps or ventouse) or a manual technique with their hands. It is thought that the hand technique may result in less trauma for women and babies but we do not yet have the information needed to make a robust recommendation about this. This study will investigate which methods for rotating the baby at birth (hand or instrument) have the best outcomes for the mother and baby, both straight after the birth and in the longer term.

### Who can participate?

Birthing people with a term baby who is positioned either 'back-to-back' or facing sideways at the pushing stage of labour, who will need a doctor to turn their baby's head into the optimal position for birth.

### What does the study involve?

A computer programme will randomly assign birthing people who consent to take part in the trial to one of two groups. One group will have manual rotation, and the second group will have instrumental rotation. The researchers will collect data to find out whether manual rotation is less likely to cause trauma to a woman's anus (back passage) and the perineum (skin between vagina and anus) without increasing the risk of caesarean birth. The researchers will also ask women about their birth experience and other important outcomes such as injury to the baby, impact on breastfeeding and their birth experience.

### What are the possible benefits and risks of participating?

As we currently don't know which method of rotating the baby's head improves outcomes, there may not be any direct benefit to taking part in the trial. As both techniques are widely used as

standard care, the risk of being randomised to one or the other is minimal. Through carrying out this trial, the researchers will be investigating the risks associated with each technique to better inform standard practice.

Where is the study run from?

The study is sponsored by University College London and is managed by the Birmingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?

May 2022 to July 2025

Who is funding the study?

National Institute for Health and Care Research (UK)

Who is the main contact?

Laura Butler, rotate@trials.bham.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Laura Butler

**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

301912

**Protocol serial number**

CPMS 52151, IRAS 301912

## Study information

**Scientific Title**

Randomised controlled trial of manual versus instrumental rotation of the fetal head in malposition at birth

**Acronym**

ROTATE

**Study objectives**

For women at full cervical dilatation with persistent malposition of the fetal head requiring a rotational assisted vaginal birth, does manual rotation of the fetal head compared to instrumental rotation with forceps or ventouse, reduce the incidence of 3rd- or 4th-degree perineal trauma (superiority hypothesis), without increasing the incidence of caesarean section birth (non-inferiority hypothesis)?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 17/05/2022, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel Royal, Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048088; surrey.rec@hra.nhs.uk), ref: 22/LO/0157

**Study design**

Randomized; Interventional; Design type: Treatment, Management of Care, Other

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Fetal head in malposition at birth

**Interventions**

Interventions (health technologies) being assessed:

**INTERVENTION – MANUAL ROTATION:** Rotation of the fetal head by manual rotation - followed by direct forceps or direct ventouse or spontaneous effort. Instrument to be used for direct traction after the rotation at the choice of the obstetrician and recorded for further analysis.

**COMPARATOR – INSTRUMENTAL ROTATION:** Rotation of the fetal head by rotational instrument (rotational forceps or rotational ventouse) at the choice of the obstetrician. Instrument to be used for direct traction after the rotation at the choice of the obstetrician – usually the same type of instrument (forceps or ventouse).

The trial needs to be pragmatic if it is to be successfully delivered, hence the need for heterogeneous interventions in the control group, something which was acknowledged in the commissioning brief 'Comparator: forceps or ventouse according to clinician expertise'; and the evidence synthesis by HTA "There was no significant difference in the risk ratio between [rotational] forceps & rotational ventouse in adverse maternal outcomes".

In a national survey (with findings also supported by the REDEFINE national audit data), most of the obstetricians considered themselves competent in manual rotation and in only one of the instrumental techniques (either ventouse or rotational forceps). We consider the sample size sufficiently large for intended instrument to be balanced by trial arm, and so do not feel that it is necessary to add this as a stratification or minimisation factor for ventouse versus forceps, particularly as this would potentially increase the burden (and time spent) at the point of randomisation.

#### INTERVIEWS - Qualitative study

In the first instance, participants will be invited to participate in an interview via telephone/video conference (e.g. Zoom, Skype or WhatsApp). To ensure inclusivity, where participants are unable to participate virtually, the researchers may consider face-to-face interviews in the clinic where they were treated/work, at the University of Birmingham or University College London (if local to either), in the participant's home or in an appropriate public space. The researchers will ensure that they are following appropriate COVID-related guidance if interviews are undertaken face-to-face. From experience, we anticipate that the vast majority will be done virtually.

For women, the researchers will aim to conduct interviews within four to eight weeks of them being approached to participate (decliners) or being randomised (women who consent to randomisation). This will however remain flexible to accommodate the needs of the women.

A discussion guide to facilitate the interviews will be developed informed by existing literature (for example the domains proposed in the Theoretical Framework for Acceptability of Healthcare Interventions [Sekhon], patient and public involvement, and discussions within the ROTATE team. Interviews will be conducted in a participant-focused manner allowing issues and perspectives important to participants to arise naturally [Clarke and Braun].

For women, interviews will explore their views and experiences of the treatment options (including perceived risks around instrumental intervention such as forceps), the recruitment approach, voluntariness, consent processes, randomisation, barriers and facilitators to participation, acceptability of randomisation, and experiences of care pre- and post-intervention.

For healthcare professionals, interviews will explore their familiarity with, and exposure to, different types of interventions (manual, instrumental); training and confidence in the different interventions; views and experiences of recruitment, consent processes, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of the intervention, and perceptions of trial processes.

Participants will be given the choice as to where an interview takes place (e.g. via phone, video call, or face-to-face). It is anticipated that a blended approach of face-to-face and virtual data collection will be used given the current COVID situation, social distancing and to maximise the facilitation of a large number of interviews/focus groups in a short period of time. There is also growing evidence that rapport can be readily established using remote techniques [Vogl]; and that the flexibility and adaptability afforded by technology minimises inconvenience and disruption to participants [Drabble; Sivell].

All participants will be asked to complete a brief demographic questionnaire prior to or at the end of the interview to facilitate purposive sampling and a description of the sample.

#### INTERIM ANALYSES

Interim analyses of safety and efficacy will be presented to the independent DMC/Trial

Oversight Committee during the trial. This is likely to include the analysis of the primary and major secondary outcomes and full assessment of safety (SAEs) at least at annual intervals. Criteria for stopping or modifying the trial based on this information will be ratified by the DMC. Details of the agreed plan will be written into a DMC Charter and the Statistical Analysis Plan

## **BIAS MINIMISATION**

**Blinding:** In this pragmatic study, given the nature of the interventions, it will not be possible to blind clinicians performing the intervention, or women, to the allocated randomised group. For key outcomes, including caesarean section as well as major neonatal trauma and morbidity, ascertainment is not prone to bias. Anal sphincter injury has to be repaired as soon as possible in the same (in most instances operating/theatre) room as the just delivered baby might have visible marks from the ventouse or forceps, which makes blinding to allocation unrealistic.

**Handling missing data:** In the first instance, analysis will be completed on received data only with every effort made to follow-up participants even after protocol violation to minimise any potential for bias. To examine the possible impact of missing data on the results, and to make sure we are complying with the intention-to-treat principle, sensitivity analyses may be performed on the primary outcome measure that will include methods such as multiple imputation.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Anal sphincter injury and Caesarean section (co-primary outcomes) measured from data collection on case report forms, including a checklist for the standardisation of perineal assessment, and documentation of the need for caesarean section. Completed immediately after birth.

## **Key secondary outcome(s)**

1. Maternal and neonatal morbidity/mortality collected on a case report form within 48 hours of birth
2. Urinary incontinence measured using the International Consultation on Incontinence Questionnaire within 48 hours of birth and at 3 months after birth
3. Fecal incontinence measured using the Fecal Incontinence Quality of Life Questionnaire within 48 hours of birth and at 3 months after birth
4. Impact on infant feeding measured using the Breastfeeding Questionnaire within 48 hours and at 3 months after birth
5. Birth experience measured using the Childbirth Experience Questionnaire within 48 hours and at 3 months after birth
6. Birth trauma measured using the CITY Birth Trauma scale at 3 months after birth

## **Completion date**

31/07/2025

## **Eligibility**

### **Key inclusion criteria**

Main study:

1.  $\geq 16$  years of age at time of randomisation
2. Singleton pregnancy
3.  $\geq 36$  weeks' gestation with cephalic presentation and persistent malposition of the fetal head

occiput between 2 and 10 o'clock (diagnosed clinically or with ultrasound) requiring a rotational operative vaginal birth

4. Birth conducted or supervised by obstetricians signed off as competent in both manual and instrumental rotation (at least one of forceps/ventouse)

Qualitative sub-study:

1. All women eligible for ROTATE and who are approached about the trial, irrespective if they agree to participate or not
2. All healthcare professionals caring for women in and involved in the delivery of ROTATE
3. Those able and willing to give informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

Female

### **Total final enrolment**

321

### **Key exclusion criteria**

Main study:

1. Women with contraindications for operative birth with either ventouse or forceps
2. Women with occiput between 11 and 1 o'clock (occipito-anterior).
3. Brow presentation
4. Intrauterine fetal death

Qualitative sub-study:

1. Participants who would be unable to take part in an interview due to language barriers (interviews will be undertaken in English)

### **Date of first enrolment**

11/09/2022

### **Date of final enrolment**

31/10/2024

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

**Study participating centre**

**University College London Hospitals**

Elizabeth Garrett Anderson Wing

25 Grafton Way

London

United Kingdom

WC1E 6DB

**Study participating centre**

**Leeds General Infirmary**

Great George Street

Leeds

United Kingdom

LS1 3EX

**Study participating centre**

**Sunderland Royal Hospital**

Kayll Road

Sunderland

United Kingdom

SR4 7TP

**Study participating centre**

**Liverpool Women's Hospital**

Crown Street

Liverpool

United Kingdom

L8 7SS

**Study participating centre**

**University Hospital Coventry**

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

**Study participating centre**

**Rosie Maternity Hospital**

Robinson Way  
Cambridge  
United Kingdom  
CB2 0SW

**Study participating centre**

**St Thomas' Hospital**

Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**

**James Cook University Hospital**

Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**

**Nottingham University Hospitals NHS Trust - City Campus**

Nottingham City Hospital  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**

**The Whittington Hospital**

Highgate Hill  
London  
United Kingdom  
N19 5NF

**Study participating centre**

**Royal United Hospital**

Combe Park

Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**University Hospital of North Tees**  
Hardwick Road  
Stockton-on-tees  
United Kingdom  
TS19 8PE

**Study participating centre**  
**Royal Infirmary of Edinburgh at Little France**  
51 Little France Crescent  
Old Dalkeith Road  
Edinburgh  
Lothian  
United Kingdom  
EH16 4SA

## Sponsor information

**Organisation**  
University College London

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127818

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the ROTATE trial team: rotate@trials.bham.ac.uk. Requests for data generated during this study will be considered by BCTU. Data will typically be available within 6 months after the primary publication unless it is not possible to share the data (for example: the trial results are to be used as part of a regulatory submission, the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).

Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the Chief Investigator and, where appropriate (or in absence of the Chief Investigator) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent Trial Steering Committee (TSC).

A formal Data Sharing Agreement (DSA) may be required between respective organisations once the release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers the transfer of patient-identifiable information, provided consent has been obtained for this transfer. Any data transfer will use a secure and encrypted method.

## IPD sharing plan summary

Available on request

### Study outputs

| Output type                                   | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a>          |               |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | version 2.0   | 21/03/2022   | 23/11/2022 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version 4.0   | 18/11/2022   | 12/12/2023 | No             | No              |
| <a href="#">Statistical Analysis Plan</a>     | version 1.0   | 24/02/2023   | 12/12/2023 | No             | No              |
| <a href="#">Study website</a>                 | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |