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

Submission date
26/10/2022

Recruitment status
No longer recruiting

Registration date
24/11/2022

Overall study status
Completed

Last Edited
29/05/2025

Condition category
Pregnancy and Childbirth

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

Integrated Research Application System (IRAS)
301912

Central Portfolio Management System (CPMS)
52151

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 and 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. ≥16 years of age at time of randomisation
2. Singleton pregnancy
3. ≥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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	21/03/2022	23/11/2022	No	Yes
Protocol file	version 4.0	18/11/2022	12/12/2023	No	No
Statistical Analysis Plan	version 1.0	24/02/2023	12/12/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes