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Standardisation, acceptability and outcomes of elective (planned) caesarean births where the baby's head is delivered first, and the baby is not fully delivered until after they have taken their first cry or 2 minutes have passed (whichever is sooner)

Submission date
22/05/2025

Recruitment status
No longer recruiting

Registration date
16/01/2026

Overall study status
Completed

Last Edited
15/01/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Whilst in the womb, a baby’s lungs are filled with fluid, which helps them grow and develop. During labour and birth, most of this fluid goes away, as the baby transitions from life in the womb to breathing air. Some babies might take longer to clear this fluid after they are born, so the lungs can remain “wet” for longer, making it harder to breathe until the fluid clears. When this happens, babies breathe faster and shallower, a condition known as Transient Tachypnea of the Newborn (TTN) and they often need some additional help with breathing, antibiotics to prevent or clear infection, and sometimes a stay in a Neonatal Intensive Care Unit.
The condition TTN is twice as common in babies born by planned caesarean than those born vaginally. Babies born via Caesarean are typically born very quickly which may not give them enough time to clear this fluid, and transition well to breathing air.
In this world-first study, we aim to assess a new way to perform a planned CB: a ‘Time-to-Transition- Caesarean Birth’. Rather than being born rapidly after opening the womb, the doctor will deliver the baby’s head and keep the body inside the womb until the baby starts to cry: a process designed to mimic the transition time which happens in vaginal births. This extra time may help the baby to transition to breathing air and has the potential to reduce the risk of TTN. As with any CB, the mother and baby will be closely monitored and if there are any concerns the baby will be immediately delivered. Everything else about the CB and recovery afterwards will remain unchanged.
Reducing “wet lungs” (and TTN) at birth could improve the experience for many families in the first few weeks after their planned caesarean birth and could result in cost-savings for the NHS. The aim of the study is to investigate if it is possible (feasible) to conduct a larger study to determine if a “Time-to-Transition caesarean birth (CB)” improves the health of newborn babies.

Who can participate?
We will recruit 34 women at Southmead Maternity Unit.
Women will be able take part if they are:
• pregnant with one baby
• planning to have Caesarean birth
• and if baby's position is "head-down"

What does the study involve?
This study will investigate the possibility of performing a "Time-to-Transition Caesarean Birth". We will video the births, so we are able to learn from each of them. We will ensure we can accurately collect health information about both mother and baby from the Hospital records and in the first four weeks after birth. We will ask women and their birth partner their views on their birth experience and ask healthcare professionals their views on the births too.
What are the possible benefits and risks of participating?
We don't know if this new method is better than a routine caesarean birth. We hope that the Time-to-Transition birth will reduce the chance your baby will have wet lungs and are less likely to need help breathing, antibiotics, or a stay in NICU. But we can't be sure. This study will help us find out. For that reason, we don't know if there will be any direct benefit to you or your baby, but you may be helping families in the future once the results of this study are known.
We don't expect the Time-to-Transition birth will be riskier to you or your baby. During all caesarean births, including a Time-to-Transition caesarean birth, the mother is monitored closely for blood loss and the baby is monitored for colour, tone, heart rate and breathing. Your baby will be birthed immediately if there are any concerns about you or your baby.

Where is the study run from?
This study is being carried out by staff at North Bristol NHS Trust and the University of the West of England. Pregnant women who are having a planned caesarean section at Southmead Maternity Unit will be approached and offered study participation by a member of their care team.

When is the study starting and how long will it run for?
March 2024 to September 2024.

Who is funding the study?
This study is funded by donations made to the Southmead Hospital Charity, Bristol (UK)

Who is the main contact?
Dr Joanna Crofts at Southmead Hospital (North Bristol NHS Trust), Joanna.Crofts@nbt.nhs.uk.

Contact information

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Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
325202

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R&D 5238

Study information

Scientific Title
Time-to-Transition Caesarean Birth Study: A study investigating the feasibility of a “Time-to-Transition Caesarean Birth”

Acronym
Time-to-Transition Caesarean Birth Study

Study objectives
During an uncomplicated CB there are seconds between opening the uterus and birth. This rapidity relates to historic concerns regarding maternal blood loss (in general the longer the uterus remains open, the greater the maternal blood loss) however, a rapid birth provides the neonate with very little time to adapt to the ex-utero

environment. This contrasts with babies born through the birth canal when the body is usually born several minutes after the head, during which time breathing and fluid drainage from the mouth frequently occurs.
These natural events may be fundamental to a successful neonatal transition; their lack during CB may contribute to the higher incidence of TTN. Slowing the birth of babies born by CB has the potential to reduce the incidence of TTN.
The intervention to be studied is novel: a 'Time-to-Transition Caesarean Birth' during which the birth of the baby from the uterus will be slowed with the intention of providing the baby with more time to transition from in-utero to ex-utero life. The CB will be conducted as per routine practice until the birth of the baby's head.
Once the baby's head has been delivered from the uterine cavity onto the maternal abdomen, the body of the baby will be left inside the uterus to allow the baby to commence spontaneous respiration whilst remaining attached to the placental circulation. The body will be delivered 30 seconds after the first cry (approximately 20 neonatal breaths) or at 120 seconds, whichever is sooner. Neonatal and maternal condition will be monitored throughout, as per routine care, and the birth will be expedited and the intervention ceased if any concerns arise.
The uterine incision will be under tension (stretched and compressed by the fetal trunk) and therefore maternal bleeding during the delayed delivery is expected to be minimal.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/08/2023, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048276; berkshireb.rec@hra.nhs.uk), ref: 23/SC/0228

Study design
Single centre observational feasibility study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Planned (elective) caesarean section

Interventions
Novel intervention called "time-to-transition caesarean birth".
Fetal head delivered first, and fetal body remains in the uterine cavity until either:
• 30 seconds have passed since first cry
OR
• 120 seconds have passed – whichever is soonest
Delivery will be expedited if there are concerns about either neonatal or maternal condition.
In a routine caesarean birth, the fetal head is delivered first, followed immediately by body (usually over a duration of two to 10 seconds).

Intervention Type
Procedure/Surgery

Primary outcome(s)

Proportion of births in which the fetal body remained in the uterine cavity after the delivery of the fetal head and shoulders until either (i) 30 seconds passed since first cry, or (ii) 120 seconds have passed (whichever is sooner) was achieved measured using patient records

Key secondary outcome(s))

1. Maternal Outcomes
1. Indication for caesarean birth is recorded from clinical records at time of delivery
2. Antenatal corticosteroid administration for fetal lung maturity is recorded from clinical records including gestational age at time of administration
3. Length of surgery is measured using operative time from knife-to-skin to wound closure recorded in theatre records at time of surgery
4. Weighed blood loss is measured using gravimetric method recorded in theatre records at time of surgery
5. Use of cell salvage and volume of blood re-infused is recorded from anaesthetic chart at time of surgery
6. Pre-operative haemoglobin is measured using full blood count from laboratory results within 24 hours prior to surgery
7. Post-operative Day 1 haemoglobin is measured using full blood count from laboratory results on Day 1 post-surgery
8. Blood pressure on admission is measured using automated sphygmomanometer and recorded in clinical notes at time of hospital admission
9. Lowest blood pressure pre-delivery in theatre is measured using anaesthetic monitoring and recorded in theatre records during surgery
10. Maternal febrile morbidity is measured using maximum recorded maternal temperature and duration of temperature ≥38°C from clinical records during hospital stay
11. Post-natal antibiotic treatment is recorded from medication administration records during postnatal hospital stay
12. Maternal length of stay is measured using admission and discharge dates from hospital records
13. Maternal readmission to hospital is recorded from hospital administrative data within 28 days post-discharge

2. Neonatal Outcomes
14. CTG classification post-regional anaesthetic is assessed using clinical interpretation of cardiotocography and recorded in clinical notes immediately following anaesthetic administration
15. Apgar scores at 1, 5 and 10 minutes are measured using standard Apgar scoring system recorded in neonatal records after complete delivery of the baby
16. Arterial and venous cord blood gases (pH, base excess, haemoglobin, haematocrit, lactate) are measured using blood gas analyser at time of delivery
17. Need for respiratory support is recorded from neonatal resuscitation records at birth and at 10 minutes of age
18. Birth weight is measured using calibrated neonatal scales at time of birth
19. Placental weight is measured using calibrated scales after delivery of placenta
20. Jaundice requiring phototherapy is recorded from neonatal clinical records during hospital stay
21. Neonatal temperature at 5 minutes of age is measured using digital thermometer and recorded in neonatal records
22. Neonatal febrile morbidity is measured using maximum recorded neonatal temperature and duration of temperature ≥38°C from clinical records during hospital stay

23. NICU admission and length of stay are recorded from neonatal unit records
24. Neonatal investigations and treatments (chest X-ray, blood tests, antibiotics) are recorded from neonatal clinical records during hospital stay
25. Neonatal length of hospital stay is measured using admission and discharge dates from hospital records

3. Patient (Maternal) and Birth Partner Reported Outcome Measures
26. Maternal birth experience is measured using Birth Experience Questionnaire (BEQ-10) at Day 1 and Day 28 post-delivery
27. Birth partner birth experience is measured using Birth Experience Questionnaire (BEQ-10) at Day 1 and Day 28 post-delivery
28. Healthcare utilisation is measured using structured questionnaire or administrative data at Day 28 post-delivery for both maternal and neonatal services beyond standard care

4. Video Quality and Location of Filming
29. Video quality is assessed using predefined criteria for clarity and completeness of footage to determine head-to-body delivery time and time from head delivery to first cry, measured from video recordings at time of caesarean birth
30. Video location is recorded as either head-mounted camera on primary surgeon or tripod /overhead light-mounted camera at time of caesarean birth

Completion date
18/09/2024

Eligibility

Key inclusion criteria
Women will be included if they are having a planned Caesarean Birth and are:
1. Aged ≥16 years
2. Singleton pregnancy
3. Cephalic presentation
4. Gestational age* at birth between 37+0 and 42+0 weeks (*determined by early ultrasound scan)
5. Willingness for caesarean birth to be filmed using Hospital cameras

Birth partners will be included if they:
1. Aged ≥16 years
2. Are present during the birth of a woman recruited into the clinical study

Participant type(s)
Patient, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
50 years

Sex
All

Total final enrolment
34

Key exclusion criteria
Women will be excluded if they:
1. Are unable to provide informed consent
2. Multiple pregnancy
3. Ruptured membranes
4. Non-cephalic presentation (e.g. breech, oblique or transverse presentations)
5. Suspected abnormally invasive placenta
6. Anterior low-lying placenta
7. Known or suspected significant fetal abnormality
8. Caesarean birth under general anaesthetic
9. Declines consent to filming

Birth partners will be excluded if they are unable to provide informed consent

Date of first enrolment
08/03/2024

Date of final enrolment
20/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
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BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Southmead Hospital Charity Research Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	18/07/2023	14/01/2026	No	Yes
Participant information sheet	version 1.3	18/07/2023	14/01/2026	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes