ISRCTN10977996 https://doi.org/10.1186/ISRCTN10977996

# ABOVE: Cerclage after Caesarean

**Submission date**
17/05/2024

**Recruitment status**
Recruiting

**Registration date**
17/05/2024

**Overall study status**
Ongoing

**Last Edited**
17/05/2024

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

Background and study aims
Recent studies have shown that if a woman has had a caesarean section in labour (when the cervix is opening) she is more likely to have a premature baby in a future pregnancy. In women who have had an in-labour caesarean section there is a 5-10% chance of a preterm birth in a subsequent pregnancy.
For women who have had an in-labour caesarean section, which was then followed by a preterm birth or mid-trimester loss, early birth is even more likely in subsequent pregnancies. Currently it is not known which treatments are most effective to stop this happening.
These women should be referred to specialist preterm clinics, which will offer them ultrasound monitoring of the length of their cervix, and they may or may not also be offered a cervical cerclage, although there are currently no national guidelines about this. This is a small surgical procedure where a stitch is placed around the cervix through the vagina (transvaginal cerclage). A cerclage can also be placed higher up, through an abdominal procedure involving a cut in the tummy (transabdominal cerclage). This procedure is a longer operation with more recovery time and means that any future babies will need to be born by caesarean section.
Both types of cerclage are offered as standard care to women at high risk of preterm birth. Although transvaginal cerclages are more straightforward, transabdominal cerclages might be more effective because they are above any damage that might have been caused during a previous caesarean section.

Who can participate?
Women who have had a preterm birth or mid-trimester loss (a loss between 14 and 24 weeks of pregnancy) after a previous caearean section in labour

What does the study involve?
Participants will be allocated to one of two treatments: a vaginally-placed cervical stitch or an abdominally-placed cervical stitch, performed before 14 weeks of pregnancy. Some women will join the study before pregnancy, in this group the abdominally-placed stitch will be sited before they get pregnant and the vaginal stitch before 14 weeks in the next pregnancy.
With both stitches participants are followed up in a prematurity clinic with regular transvaginal scanning. If the cervix becomes short participants may be admitted to hospital or offered other treatments (such as a steroid injection to help the baby's lungs mature, and/or putting in an additional stitch if the cervix opens). These may be offered if there is a high chance the baby may be born very early.

The researchers will ask your permission to look at participants' medical notes after delivery to find out what happened. They may also save some scan images of the cervix taken in the prematurity clinic.

What are the possible benefits and risks of participating?
Taking part in the study may not have any direct benefit to participants now. However, the results of this study might help to improve care in any future pregnancies as well as other women, and to reduce the number of babies being born too early.
Having a cervical stitch inserted is a relatively common procedure and is known to help some women. Risks of both treatments include post-operative pain, infection and bleeding. The uncommon risks (occurring in 1 out of 1000) include tearing of the cervix or bladder. The obstetrician would generally be able to repair any tearing to the cervix immediately. A tear to the bladder would require another operation by a urologist (a medical doctor with specialist training in problems of the urinary tract). Both would require a few extra days in hospital. If the doctor is worried about infection, a swab may be taken from the vagina and, if there is evidence of infection, participants may be given a course of antibiotics. While it is likely that either of the cerclages will reduce the chance of miscarriage or preterm birth, they will not entirely eliminate the possibility.

Where is the study run from?
St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2023 to October 2026

Who is funding the study?
1. Action Research Medical (UK)
2. Borne (UK)

Who is the main contact?
above-study@kcl.a.c.uk

# Contact information

### Type(s)
Public, Scientific


### Contact name
Prof Andrew Shennan

### ORCID ID
https://orcid.org/0000-0001-5273-3132

### Contact details
Women's and Children's Department
10th Floor
St Thomas Hospital Westminster
Bridge Road
London
United Kingdom
SE1 7EH

+44 (0)20 7188 7188
andrew.shennan@kcl.ac.uk

**Type(s)**
Public, Scientific

**Contact name**
Dr Laura van der Krogt

**ORCID ID**
https://orcid.org/0009-0004-2040-0375

**Contact details**
Women's and Children's Department
10th Floor
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)20 7188 7188
laura.c.van_der_krogt@kcl.ac.uk

**Type(s)**
Public, Scientific

**Contact name**
Dr Jenny Carter

**Contact details**
Women's and Children's Department
10th Floor
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)20 7188 7188
jenny.carter@kcl.ac.uk

# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Integrated Research Application System (IRAS)**
327879

**ClinicalTrials.gov (NCT)**
Nil known

### Protocol serial number
CPMS 59777, IRAS 327879

# Study information

### Scientific Title
Cerclage after Caesarean: a randomised controlled trial to assess the optimal preventative management for preterm birth secondary to caesarean section damage (ABOVE)

### Acronym
ABOVE

### Study objectives
Transabdominal cerclage (TAC) will be more effective than transvaginal cerclage (TVC) in reducing mid-trimester pregnancy loss (MTL) and spontaneous preterm birth (PTB) in women with experience of MTL/spontaneous preterm birth (sPTB) after in-labour caesarean section (CS).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approval 15/05/2024, North West - Preston Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, UK; +44 (0)2071048364; preston.rec@hra.nhs.uk), ref: 24 /NW/0093

### Study design
Randomized; Interventional; Design type: Treatment, Surgery

### Primary study design
Interventional

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Preterm birth secondary to caesarean section

### Interventions
ABOVE is a multi-centre randomized controlled trial comparing TAC or TVC as a preventative strategy for sPTB in women with a history of sPTB or MTL after an in-labour caesarean section.

Participants will be allocated to either Group A or Group B depending on whether they are already pregnant or planning a pregnancy. The trial is separately powered for these two groups; Group A: in pregnancy and Group B: pre-conception.

160 participants with complete data in total (80/group) with a history of term CS in labour, followed by a subsequent pregnancy loss or sPTB (defined as MTL between 14+0-23+6 weeks or sPTB <30 weeks), either planning a pregnancy, or <14 weeks pregnant <14 weeks pregnant (Group A) or planning a pregnancy (Group B), will be recruited. To allow for loss to follow up, and Group B participants not becoming pregnant within the 18 recruitment period.

Eligible women referred to specialist preterm birth services, either for pre-pregnancy counselling or pregnancy surveillance, will be offered the opportunity to take part in this trial. Pregnant participants (<14 weeks gestation) will be allocated to Group A, while women planning a pregnancy will be allocated to Group B.

Participants will be randomised (1:1) through the ABOVE trial database, which will be hosted within the Medscinet PCN Database (https://www.medscinet.net/ukpcn; REC reference 22/ES /01; IRAS 308157). Women will be randomised to one of the two preventative treatments: 1) TAC, or 2) TVC

It is important to separately evaluate pre-conception and in-pregnancy TACs. The suture can be placed higher pre-conception and this may provide better support around scar weakness. Efficacy could therefore be different in these populations so separately powered trials are planned.

Once randomisation has occurred, the allocated procedure will be arranged. A cervical cerclage will be inserted. The choice of cerclage insertion technique and anaesthesia will be at the local clinician's discretion with all details recorded on the trial database. Participants in Group A will have the cerclage (TAC or TVC) inserted prior to 14 weeks'
gestation, usually under regional anaesthetic. Group B participants allocated to TAC will have the procedure placed pre-conceptually and those allocated to TVC will have it placed before 14 weeks' gestation (depending on the time point at study entry and randomisation). TACs are performed as as an open or laparoscopic procedure under either regional or general anaesthetic, requiring an inpatient stay of up to 3 days. TVCs will be performed at the participant's local maternity unit with the insertion technique and anaesthesia according to the clinician's discretion and local practices. TACs will usually remain in-situ (to support any future pregnancies) while TVCs are removed at around 37 weeks' gestation. TACs are more specialised procedures and so, if unavailable locally, they may be carried out in tertiary specialist units. The time frame between randomisation and study procedure is flexible from site to site, depending on theatre list availability, although all procedures must be carried out before 14 weeks' gestation.

There will be no additional research visits, and all preterm care will continue according to local participating site protocols.

Demographic, ongoing preterm surveillance (including cervical length measurements) and outcome data will be collected by recruiting sites from hospital electronic records and entered directly into the study database. Participant identifiers (initials, date of birth, hospital and NHS number) are kept on a separate but linked Medscinet database which is only accessible to authorised site users.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
The occurrence of mid-trimester pregnancy loss or spontaneous preterm birth before 30 weeks of gestation, collected from the patient's medical records

## Key secondary outcome(s))
Maternal:
1. Admission to hospital for symptoms of threatened preterm labour

2. Administration of antenatal corticosteroids for fetal lung maturation
3. Administration of magnesium sulphate for fetal cerebral protection.
4. Transfer to other hospitals for neonatal cot availability (in-utero transfer)
5. Time between intervention and delivery
6. Requirement for additional emergency/rescue cerclage
7. Serious complications occurring as a result of trial intervention: bladder injury, bowel injury, intraoperative rupture of membranes, cervical tear, hysterectomy
8. Maternal sepsis
9. Admission to ITU
10. Maternal death

Neonatal:
1. Gestation at birth
2. Birthweight
3. Apgar scores (if available)
4. Days before discharge home (up to 28 days)
5. Admission to neonatal unit
6. Neonatal infection
7. In utero fetal death after 14 weeks
8. Stillbirth
9. Neonatal death

Collected from the patient's medical records at time of birth unless stated otherwise

### Completion date
01/10/2026

## Eligibility

### Key inclusion criteria
Women will be eligible for the trial if they are:
1. Willing and able to give informed consent
2. Aged 16 years or above
3. Have had a previous term in-labour caesarean section (between 4 and 10 cm dilated) followed by an MTL (> 14 weeks) or preterm birth (<30 weeks)
4. Pregnant, but will be less than 14+0 weeks' gestation at the time of the allocated intervention (Group A) OR
5. Not yet pregnant but considering a further pregnancy (Group B)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 years

### Sex
Female

### Key exclusion criteria
Potential participants will not be eligible for the trial if:
1. They are more than 14+0 weeks pregnant at the time of randomisation (as insertion of TAC is associated with higher risk beyond this gestation)
2. They already have a cerclage or (Arabin) pessary in situ
3. They are not planning another pregnancy
4. They have a history of preterm birth (spontaneous/iatrogenic) prior to the term emergency section
5. They are pregnant and expecting more than one baby (multiple pregnancy)

### Date of first enrolment
01/07/2024

### Date of final enrolment
01/01/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**St Thomas' Hospital**
Westminster Bridge Road
London
United Kingdom
SE1 7EH

### Study participating centre
**Uclh**
250 Euston Road
London
United Kingdom
NW1 2PQ

### Study participating centre
**Rosie Hospital**
Robinson Way

Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**Liverpool Womens Hospital**
Crown Street
Liverpool
United Kingdom
L8 7SS

**Study participating centre**
**Leicester General Hospital**
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

**Study participating centre**
**The Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

**Study participating centre**
**Chelsea and Westminster Hospital**
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

**Study participating centre**
**West Middlesex University Hospital**
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

**Study participating centre**
**Sunderland Royal Hospital**
Kayll Road
Sunderland
United Kingdom
SR4 7TP

**Study participating centre**
**Heartlands Hospital**
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

**Study participating centre**
**Birmingham Womens Hospital**
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

**Study participating centre**
**St Michaels Hospital**
St. Michaels Hospital
Hayle
United Kingdom
TR27 4JA

**Study participating centre**
**Royal United Hospital**
Combe Park
Bath
United Kingdom
BA1 3NG

**Study participating centre**
**Princess Anne Hospital**
Coxford Road
Southampton

United Kingdom
SO16 5YA

**Study participating centre**
**Southmead Hospital**
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

**Study participating centre**
**Poole Hospital**
Longfleet Road
Poole
United Kingdom
BH15 2JB

**Study participating centre**
**St James's University Hospital**
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

**Study participating centre**
**Leeds General Infirmary**
Great George Street
Leeds
United Kingdom
LS1 3EX

**Study participating centre**
**Royal Hampshire County Hospital**
Romsey Road
Winchester
United Kingdom
SO22 5DG

**Study participating centre**
**St Richards Hospital**
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

**Study participating centre**
**John Radcliffe Hospital**
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**Kent and Canterbury Hospital**
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

**Study participating centre**
**University Hospital Coventry**
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

**Study participating centre**
**Barnet Hospital**
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

**Study participating centre**
**Royal London Hospital**
Whitechapel
London

United Kingdom
E1 1BB

**Study participating centre**
**Conquest Hospital**
The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7RD

# Sponsor information

**Organisation**
King's College London

**ROR**
https://ror.org/0220mzb33

# Funder(s)

**Funder type**
Charity

**Funder Name**
Action Medical Research; Grant Codes: GN2967

**Alternative Name(s)**
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

**Funder Name**

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available and will be stored in a non-publicly available repository. Data will be stored on the ABOVE Trial Database, which is hosted within the already established PCN Database (https://www.medscinet.net/ukpcn). This is a secure web-based platform containing standardised clinical information regarding women at high risk of spontaneous preterm birth. Participant identifiers are kept on a secure separate but linked Medscinet “Patient Details” database, which is only accessible to authorised site users and the PCN Database Project Manager (where the ABOVE study database is hosted) for providing user access and assistance in resolving queries.

## IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Group A version 3.0 | | 17/05/2024 | No | Yes |
| Participant information sheet | Group B version 3.0 | | 17/05/2024 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |