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C-STICH2: Rescue cervical stitching to prevent miscarriage and premature birth

Submission date
11/06/2018

Recruitment status
No longer recruiting

Registration date
13/06/2018

Overall study status
Ongoing

Last Edited
31/10/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
A cervical cerclage is the placement of a stitch to keep the neck of the womb (cervix) closed. A stitch can be placed in a planned way because of a perceived risk of premature birth based on a woman's pregnancy history or because the neck of the womb is shorter than normal on an ultrasound scan but still closed. Sometimes the neck of the womb can start to open early and the bag of water around the baby (amniotic sac) can come through the neck of womb. If this happens between 16 and 28 weeks of pregnancy an emergency rescue stitch can be performed to try and delay delivery. Prolonging the pregnancy so that the baby can be born when they are bigger and stronger may give them a better chance of surviving and suffering from fewer complications of prematurity. Doctors do not know if a rescue cerclage works. There is some evidence it may prolong pregnancy but it is possible that it may also speed up delivery by causing infection or cause damage to the neck of the womb of the mother. It is therefore very important to perform a study to decide if rescue cerclages delay delivery and if it does whether this benefits the baby (and mother). The best way to work out if rescue cerclage works, and is safe, is to ask women to be randomly allocated to the treatment. This is what we need to do to ensure we know what is best for future women and babies to prevent harm. This study will ask women who have an open neck of the womb with the bag of waters around the baby coming through, to have either a rescue stitch or no rescue stitch the treatment arm will be decided by a process that randomly allocate to one group or the other. All women in the study irrespective of the allocated group will be able to have other treatments that may help prolong pregnancy such as antibiotics, progesterone and medicines that stop the womb contracting (although none of these have been proven to delay labour or improve health of babies). The study team will collect what happens to the mum and baby from their medical notes. All babies will also be reviewed at 2 years of age to assess how they are developing by a postal questionnaire completed by the parents.

Who can participate?
Women who have an open neck of the womb with the bag of waters around the baby coming through at 16-27 weeks of pregnancy..

What does the study involve?
Women will be randomly allocated to receive the stitch or not. All women in the study, whether

they have the stitch or not, will be able to have other treatments that may help prolong pregnancy such as antibiotics, progesterone and medicines that stop the womb contracting (although none of these have been proven to delay labour or improve health of babies).

What are the possible benefits and risks of participating?
Risks relating the the rescue cervical cerclage will be detailed to you by the doctor looking after you, but include infection, bleeding, failure to perform the procedure, and rupture of the membranes around your baby leading to delivery of the baby. The potential benefit of rescue cervical cerclage in terms of prolonging pregnancy is not known.

Where is the study run from?
Birmingham Women's Hospital

When is the study starting and how long is it expected to run for?
July 2018 to February 2027

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Kiran Sunner, K.K.Sunner@bham.ac.uk
(updated 12/04/2021, previously: Dr Katie Morris, r.k.morris@bham.ac.uk)

Study website
https://www.birmingham.ac.uk/C-STICH2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-005627-32

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
C-STICH2: Rescue cervical cerclage to prevent miscarriage and preterm birth: A randomised controlled, multicentre trial (RCT) with internal pilot, a nested qualitative study and cost-effectiveness analysis.

Acronym
C-STICH2

Study objectives
Does a rescue cervical cerclage prolong pregnancy when performed at 16-28 weeks at amniotic sac prolapse?

Ethics approval required
Old ethics approval format

Ethics approval(s)
We anticipate submitting for ethics approval on 01/08/2018.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available at time of registration

Health condition(s) or problem(s) studied
Obstetrics: Mid Trimester Miscarriage and Preterm Birth

Interventions

Women will be randomised via a web based application provided by the Birmingham Clinical Trials Unit.
Women will be randomised to rescue cerclage, an emergency cervical cerclage performed as quickly as feasible, or expectant management which will be pragmatic and involve other treatment at the discretion on the clinician caring for the women.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pregnancy loss rate (miscarriage and perinatal mortality, including any stillbirth or neonatal death in the first week of life)

Secondary outcome measures
Maternal (from medical records):
1. Time from conception to pregnancy end (any reason)
2. Miscarriage and pre-viable neonatal death (defined as delivery <24 weeks)
3. Stillbirth (defined as interuterine death >=24 weeks)
4. Gestation at delivery (in live births >= 24 weeks)
5. Gestational age <28/<32/<37 weeks at delivery (in live births >= 24 weeks)
6. Time from conception to onset of spontaneous vaginal delivery (in live births >= 24 weeks)
7. Sepsis (at any time in pregnancy and until 7 days postnatal)
8. Preterm pre-labour rupture of membranes (PPROM)
9. Gestational age at PPROM
10. Mode of initiation of labour (spontaneous or induced)
11. Mode of delivery (vaginal or operative vaginal or caesarean)
12. Cerclage placement complications (cervical laceration/bleeding from cervix/ruptured membranes/bladder injury)
13. Cerclage removal complications (cervical tears/need for anaesthetic/difficult to remove)
14. Other maternal complications: vaginal bleeding/steroid use/chorioamnionitis/maternal pyrexia of 38°C (intrapartum/postnatal)/systemic infection requiring antibiotics (intrapartum /postnatal)/admission to HDU or ITU (pre/post-delivery)
15. Serious adverse events

Neonatal (from medical records):
16. Early neonatal death (defined as a death within 7 days after delivery)
17. Late neonatal death (defined as a death beyond 7 days and before 28 days after delivery)
18. Birth weight adjusted for gestational age and sex (in live births >= 24 weeks)
19. Small for gestational age and sex (<10th centile; in live births >= 24 weeks)
20. Resuscitation at birth/additional care required (SCBU/NICU/HDU/transitional)/length of stay in additional care
21. Antibiotics within 72 hours/sepsis (clinically diagnosed/proven)
22. Early neurodevelopmental morbidity (severe abnormality on cranial ultrasound scan)
23. Respiratory support (ventilation/CPAP)/days on respiratory support/supplementary oxygen requirements at 36 weeks post-menstrual age
24. Necrotising enterocolitis (Bell’s stage 2 or 3)
25. Retinopathy of prematurity requiring laser treatment/disabilities/congenital abnormalities
26. Serious adverse events

Infant (from medical records):
27. Infant death after 28 days until 21 years

Child (2-year outcomes collected through a general health questionnaire and PARCA-R):
28. Non-verbal cognition
29. Linguistic skills (from vocabulary and sentence complexity sub-scales)
30. Parent report composite score (from 1 and 2)

Overall study start date
01/07/2018

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Aged 16 years or older
2. Cervical dilatation with exposed, unruptured foetal membranes
3. Singleton pregnancy
4. Gestational age 16+0 to 27+6 weeks
5. Able to give informed written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
260

Key exclusion criteria
1. Contraindication to rescue cerclage as judged by the clinician
2. Cervical cerclage (vaginal or abdominal) inserted earlier in this pregnancy

Date of first enrolment
01/01/2019

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Katie Morris
Birmingham Women's Hospital
Birmingham
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B15 2TT

Sponsor information

Organisation
Birmingham Women's and Children's NHS foundation trust.

Sponsor details
Mindelsohn Way, Birmingham B15 2TG
birmingham
England
United Kingdom
b152TG

Sponsor type
Hospital/treatment centre

Website
https://bwc.nhs.uk/birmingham-womens-hospital

ROR
https://ror.org/056ajev02

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
K.K.Sunner@bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/08/2021	26/09/2023	Yes	No