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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/06/2018		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
13/06/2018	Ongoing	Results		
Last Edited	Condition category	Individual participant data		
31/10/2024	Pregnancy and Childbirth	[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

Contact name

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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 United Kingdom 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?
<u>Protocol article</u>		11/08/2021	26/09/2023	Yes	No