

Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)

Submission date 27/11/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 03/12/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/09/2024	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Every year about 3750 women in the UK will have complications where their cervix (the neck of the womb) becomes loose and opens during the early months of pregnancy. This can require a stitch being sewn into the cervix in an attempt to keep it closed. This is often referred to as 'cervical suture' or 'cervical cerclage'. If this procedure is not performed the cervix can open too early and can result in a miscarriage or premature birth. Inserting a stitch into the cervix does not guarantee to keep the cervix closed, but it can sometimes allow the pregnancy to continue for a few more weeks. The stitches used for this procedure are available in different sizes and materials. Some of the stitch threads are made from a single, smooth fibre (e.g. nylon) while others are composed of many fibres which are woven to form a fine braided or net-like structure. A survey of consultants in the UK has shown most use braided threads when they stitch the cervix merely because it is the traditional material used and because it is thought to offer strength and enhanced support to an otherwise loose cervix. However, this survey also revealed that some surgeons thought that bacteria could grow more easily in the spaces of the braided thread than on the surface of the monofilament line. This could increase the risk of infection, which might cause an early labour. It is therefore essential to investigate whether the type of thread used for stitching the cervix increases or decreases the risk of infection. This study will therefore compare outcomes from the use of either smooth or braided stitches during this procedure.

Who can participate?

Eligible pregnant women can opt to be part of the study if they are due a planned stitch in their cervix between 12 and 22 weeks into their pregnancy.

What does the study involve?

The best way to compare the two methods of treatment is to undertake a clinical trial where the nature of the stitch used is decided randomly. Participants will be randomly allocated to receive either a monofilament suture or a braided suture to place a cervical cerclage. Apart from the type of thread used, participants will receive identical medical treatment to those not taking part in the study. Information will be collected concerning the risk of losing a baby during

pregnancy or within a week of birth, the number of weeks the pregnancy lasted prior to birth, whether the baby was admitted to a Neonatal Unit, the length of stay in the unit and any sign of vaginal or womb infection.

What are the possible benefits and risks of participating?

As any participant has been advised that they will need a cervical stitch they will not gain any additional benefit by taking part in the study. Similarly, there are no additional risks associated with taking part above those associated with the cerclage itself. Seeing what bacteria grow on the vaginal swab and removed stitch will help doctors decide if the woman taking part in the study needs any antibiotics. By taking part participants will help doctors decide which is best type of thread to offer to women requiring a cervical stitch in the future. The results of this study can potentially save the lives of more than 300 babies a year in the UK alone who would otherwise be at risk of severe prematurity or miscarriage.

Where is the study run from?

Abertawe Bro Morgannwg University Health Board, Aneurin Bevan University Health Board, Barking, Havering and Redbridge University Hospitals NHS Trust, Barts Health NHS Trust, Bedford Hospital NHS Trust, Betsi Cadwaladr University Health Board, Birmingham Women's and Children's NHS Foundation Trust, Blackpool Teaching Hospitals NHS Foundation Trust, Bolton NHS Foundation Trust, Central Manchester University Hospitals NHS Trust, Chelsea and Westminster Hospital NHS Foundation Trust, City Hospitals Sunderland NHS Foundation Trust, East Lancashire Hospitals NHS Trust, Epsom and St Helier University Hospitals NHS Trust, Guy's and St Thomas' NHS Foundation Trust, Heart of England NHS Foundation Trust, Imperial College Healthcare NHS Trust, Kettering General Hospital NHS Trust, Kingston Hospital NHS Foundation Trust, Lancashire Teaching Hospitals NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust, Lewisham and Greenwich NHS Trust, Liverpool Women's NHS Foundation Trust, Luton and Dunstable University Hospital NHS Foundation Trust, Mid Essex Hospitals NHS Trust, Milton Keynes University Hospital NHS Foundation Trust, NHS Fife, NHS Grampian, NHS Lothian, Northern Devon Healthcare NHS Trust, Nottingham University Hospitals NHS Foundation Trust, Pennine Acute Hospitals NHS Trust, Portsmouth Hospitals NHS Trust, Princess Alexandra Hospital NHS Trust, Sandwell and West Birmingham Hospitals NHS Trust, The Mid Yorkshire Hospitals NHS Trust, The Newcastle Upon Tyne NHS Foundation Trust, The Royal Wolverhampton NHS Trust, The Shrewsbury and Telford Hospital NHS Trust, Torbay and South Devon NHS Foundation Trust, University College London Hospitals NHS Foundation Trust, University Hospitals Bristol NHS Foundation Trust, University Hospitals Coventry and Warwickshire NHS Trust, University Hospitals of Leicester NHS Trust, Warrington and Halton Hospitals NHS Foundation Trust, Western Sussex Hospitals NHS Trust, Worcestershire Acute Hospitals NHS Trust, York Teaching Hospital NHS Foundation Trust.

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

March 2015 to July 2021

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?

1. Max Hughes (public)

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2. Mr Phil Tooze-Hobson (scientific)

Contact information

Type(s)

Public

Contact name

Mr Max Hughes

Contact details

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Type(s)

Scientific

Contact name

Mr Phil Tooze-Hobson

Contact details

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Birmingham
United Kingdom
B15 2TG

Additional identifiers**Protocol serial number**

5.0; HTA 13/04/107

Study information**Scientific Title**

Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)

Acronym

C-STICH

Study objectives

Every year approximately 3750 women in the UK will have complications where their cervix (the neck of the womb) becomes loose and opens during the early months of pregnancy. This can require a stitch being sewn into the cervix in an attempt to keep it closed. This is often referred to as 'cervical suture' or 'cervical cerclage'. If this procedure is not performed the cervix can open

too early and can result in a miscarriage or premature birth. Inserting a stitch into the cervix does not guarantee to keep the cervix closed, but it can sometimes allow the pregnancy to continue for a few more weeks.

The stitches used for this procedure are available in different sizes and materials. Some of the stitch threads are made from a single, smooth fibre (e.g. nylon) while others are composed of many fibres which are woven to form a fine braided or net-like structure. A survey of consultants in the UK has shown most use braided threads when they stitch the cervix merely because it is the traditional material used and because it is thought to offer strength and enhanced support to an otherwise loose cervix. However, this survey also revealed that some surgeons thought that bacteria could grow more easily in the spaces of the braided thread than on the surface of the monofilament line. This could increase the risk of infection which might cause an early labour. It is therefore essential to investigate whether thread-type used for stitching the cervix increases or decreases risk of infection.

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/1304107>

Protocol can be found at <http://www.birmingham.ac.uk/Documents/college-mds/trials/bctu/C-stich/CSTICH-protocol-V5.0-23-Mar-2017-clean.pdf>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire & Hertfordshire (East of England), 04/03/2015, ref: 14/EE/1293

Primary study design

Interventional

Study design

Multicentre open randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Insufficient cervix

Interventions

Participants will be randomly allocated to receive either a monofilament suture or a braided suture to place a cervical cerclage. Apart from the type of thread used, participants will receive identical medical treatment to those not taking part in the study. Information will be collected concerning the risk of losing a baby during pregnancy or within a week of birth, the number of weeks the pregnancy lasted prior to birth, whether the baby was admitted to a Neonatal Unit, the length of stay in the unit and any sign of vaginal or womb infection.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Pregnancy loss rate (i.e. miscarriage and perinatal mortality, defined as any stillbirth or neonatal death in the first week of life), collected from the medical records at 7 days after delivery

Key secondary outcome(s)

Current secondary outcome measures as of 22/09/2017:

Maternal outcomes, collected at discharge from hospital or 7 days, whichever is sooner:

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 PPRM
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 outcomes, collected from the medical records at 28 days for babies born at term and at the estimated delivery date for babies born preterm:

1. Early neonatal death (defined as a death within 7 days after delivery)
2. Late neonatal death (defined as a death beyond 7 days and before 28 days after delivery)
3. Birth weight adjusted for gestational age and sex (in live births ≥ 24 weeks)
4. Small for gestational age and sex (<10th centile; in live births ≥ 24 weeks)
5. Resuscitation at birth/additional care required (SCBU/NICU/HDU/transitional)/length of stay in additional care
6. Antibiotics within 72 hours/sepsis (clinically diagnosed/proven)
7. Early neurodevelopmental morbidity (severe abnormality on cranial ultrasound scan)
8. Respiratory support (ventilation/CPAP)/days on respiratory support/supplementary oxygen requirements at 36 weeks post menstrual age
9. Necrotising enterocolitis (Bell's stage 2 or 3)
10. Retinopathy of prematurity requiring laser treatment/disabilities/congenital abnormalities
11. Serious adverse events

Microbiological outcomes, measured at cerclage placement and removal:

Full cultures will be undertaken to identify the complete range of potentially pathogenic bacteria isolated from the suture, and high vaginal area. The likely significance of microorganisms isolated from each clinical sample will be assessed in the context of clinical evidence of infection in the mother and her baby.

Previous secondary outcome measures:

Maternal:

1. Gestation at delivery
2. Mode of initiation of labour
3. Mode of delivery

4. Adverse events: suture-related cervical tears, chorioamnionitis, maternal pyrexia of 38C, systemic infection requiring antibiotics (infection parameters based on Centre for Disease Control/National Healthcare Safety Network [CDC/NHSN] guidance)

Neonatal:

1. Late neonatal death, defined as a death beyond 7 days and before 28 days after delivery
2. Length of stay in neonatal unit (including level of care)
3. Severe abnormality on cranial ultrasound scan
4. Oxygen dependency at 36 weeks corrected gestation
5. Necrotising enterocolitis (Bell's stage 2 or 3)
6. Retinopathy of prematurity requiring laser treatment

Microbiological:

Full cultures will be undertaken to identify the complete range of potentially pathogenic bacteria isolated from the suture and cervix. The likely significance of microorganisms isolated from each clinical sample will be assessed in the context of clinical evidence of infection in the mother and her baby.

Completion date

31/07/2021

Eligibility

Key inclusion criteria

1. Singleton pregnancy
2. Indication for cervical cerclage (any of the below):
 - 2.1. A history of three or more previous midterm losses or premature births (≤ 28 weeks)
 - 2.2. Insertion of cervical sutures in previous pregnancies
 - 2.3. A history of midtrimester loss or premature birth with a shortened (≤ 25 mm) cervix
 - 2.4. Women whom clinicians deem to be at risk of preterm birth either by history or the results of an ultrasound scan and in whom the placement of a cervical cerclage is considered the most appropriate treatment
3. Aged 18 and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

Key exclusion criteria

Current exclusion criteria as of 07/06/2017:

1. Women who have taken part in C-STICH previously
2. Women aged less than 18 years old at the time of presentation
3. Those with a multiple pregnancy
4. Those requiring a rescue cerclage*
5. Women who are unwilling or unable to give informed consent
6. Those in whom a cerclage will be placed by any route other than vaginally (e.g. via an abdominal route)
7. Immediate need for insertion of a suture**
8. Women who have membranes that have ruptured or are surfacing***

* For study purposes, rescue cerclage is defined as: emergency cerclage where stitches are inserted in women who have had their preterm labours (e.g. uterine contractions, progressive cervical dilatation, bulging membranes) sufficiently halted by tocolysis or other means between 15 and 28 weeks.

** Immediate need for insertion of a suture should not be delayed by the trial (thus, if giving information about the trial and waiting for the participant to decide upon whether or not she wants to participate will delay the insertion of an urgently needed suture, then treatment should go ahead and the woman should be excluded from the trial).

***Woman with membranes that are ruptured or bulging through the external OS should have a rescue cerclage and be excluded from trial participation.

Previous exclusion criteria:

1. Women aged less than 16 years old at the time of presentation
2. Those with a multiple pregnancy
3. Those requiring a rescue cerclage
4. Women who are unwilling or unable to give informed consent

Date of first enrolment

01/03/2015

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Study participating centre

Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TG

Study participating centre
Royal Infirmary
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
University College Hospital
London
United Kingdom
NW1 2BU

Study participating centre
St. Mary's Hospital, Paddington
London
United Kingdom
W2 1NY

Study participating centre

Royal London Hospital

London

United Kingdom

E1 1BB

Study participating centre

University College London Hospital (UCLH)

London

United Kingdom

NW1 2BU

Study participating centre

St. Thomas' Hospital

London

United Kingdom

SE1 7EH

Study participating centre

Queen Charlotte's Hospital

London

United Kingdom

W12 0HS

Study participating centre

Chelsea and Westminster Hospital

London

United Kingdom

SW10 9NH

Study participating centre

St James's University Hospital

Leeds

United Kingdom

LS9 7TF

Study participating centre

Whipps Cross University Hospital
London
United Kingdom
E11 1NR

Study participating centre
North Manchester General Hospital
Manchester
United Kingdom
M8 5RB

Study participating centre
Royal Bolton Hospital
Bolton
United Kingdom
BL4 0JR

Study participating centre
St Mary's Hospital
Manchester
United Kingdom
M13 9WL

Study participating centre
Queen Margaret Hospital
Dunfermline
United Kingdom
KY12 0SU

Study participating centre
Heartlands Hospital
Birmingham
United Kingdom
B9 5SS

Study participating centre

Victoria Hospital
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Kettering General Hospital
Kettering
United Kingdom
NN16 8UZ

Study participating centre
University Hospital Coventry
Coventry
United Kingdom
CV2 2DX

Study participating centre
Burnley General Hospital
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Royal Blackburn Hospital
Blackburn
United Kingdom
BB2 3HH

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

Study participating centre

Newham University Hospital
London
United Kingdom
E13 8SL

Study participating centre
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Liverpool Women's Hospital
Liverpool
United Kingdom
L8 7SS

Study participating centre
Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Birmingham City Hospital
Birmingham
United Kingdom
B18 7QH

Study participating centre

Kingston Hospital
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
St Michael's Hospital
Bristol
United Kingdom
BS2 8EG

Study participating centre
Princess Royal Hospital
Telford
United Kingdom
TF1 6TF

Study participating centre
Queen's Hospital
Romford
United Kingdom
RM7 0AG

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre

St Richard's Hospital
Chichester
United Kingdom
PO19 6SE

Study participating centre
Nevill Hall Hospital
Abergavenny
United Kingdom
NP7 7EG

Study participating centre
Royal Gwent Hospital
Newport
United Kingdom
NP20 2UB

Study participating centre
New Cross Hospital
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Dewsbury Hospital
Dewsbury
United Kingdom
WF13 4HS

Study participating centre
Pinderfields Hospital
Wakefield
United Kingdom
WF1 4DG

Study participating centre

York Hospital
York
United Kingdom
YO31 8HE

Study participating centre
North Devon District Hospital
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Warrington Hospital
Warrington
United Kingdom
WA5 1QG

Study participating centre
Singleton Hospital
Swansea
United Kingdom
SA2 8QA

Study participating centre
Bedford Hospital
Bedford
United Kingdom
MK42 9DJ

Study participating centre
Broomfield Hospital
Chelmsford
United Kingdom
CM1 7ET

Study participating centre

Princess Alexandra Hospital

Harlow

United Kingdom

CM20 1QX

Study participating centre

Milton Keynes Hospital

Milton Keynes

United Kingdom

MK6 5LD

Study participating centre

Aberdeen Maternity Hospital

Aberdeen

United Kingdom

AB25 2ZL

Study participating centre

Torbay Hospital

Torbay

United Kingdom

TQ2 7AA

Study participating centre

University Hospital Lewisham

Lewisham

United Kingdom

SE13 6LH

Study participating centre

Queen Elizabeth Hospital, Woolwich

Woolwich

United Kingdom

SE18 4QH

Study participating centre

Worcestershire Royal Hospital

Worcester
United Kingdom
WR5 1DD

Study participating centre

Epsom Hospital

Epsom
United Kingdom
KT18 7EG

Study participating centre

St Helier Hospital

Carshalton
United Kingdom
SM5 1AA

Study participating centre

Luton and Dunstable University Hospital

Luton
United Kingdom
LU4 0DZ

Study participating centre

Wrexham Maelor Hospital

Wrexham
United Kingdom
LL13 7TD

Study participating centre

Ysbyty Glan Clwyd

Rhyl
United Kingdom
LL18 5UL

Study participating centre

Ysbyty Gwynedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Birmingham Women's Hospital

ROR
<https://ror.org/00xe5zs60>

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored on a secure server at Birmingham Clinical Trials Unit, with ethics and consent.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	22/10/2022	24/10/2022	Yes	No
Results article		01/08/2024	10/09/2024	Yes	No
Protocol article		28/09/2021	30/09/2021	Yes	No
HRA research summary	Participant information sheet		28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes