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

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

#### 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)

m.hughes@bham.ac.uk

2. Mr Phil Toozs-Hobson (scientific)

# **Contact information**

#### Type(s)

Public

#### Contact name

Mr Max Hughes

#### Contact details

Birmingham Clinical Trials Unit Institute of Applied Health Research University of Birmingham Birmingham United Kingdom B15 2TT +44 (0)121 414 7023 CSTICH@trials.bham.ac.uk

#### Type(s)

Scientific

#### Contact name

Mr Phil Toozs-Hobson

#### Contact details

Birmingham Women's and Children's Hospital NHS Foundation Trust Birmingham Women's Hospital Mindelsohn Way Edgbaston 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

#### Study design

Multicentre open randomised controlled trial

#### Primary study design

Interventional

#### 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 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 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)
- 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] quidance)

#### 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 ( $\leq 25$  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

#### 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

#### Royal London Hospital

London United Kingdom E1 1BB

NW1 2BU

Study participating centre
University College London Hospital (UCLH)
London
United Kingdom

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

#### 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

#### 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

#### **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

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

#### 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

#### 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

#### 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

#### 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

#### 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

#### 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		22/10/2022	24/10/2022	Yes	No
Results article		01/08/2024	10/09/2024	Yes	No
<u>Protocol article</u>	protocol	28/09/2021	30/09/2021	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes