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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

Registration date
03/12/2014

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
m.hughes@bham.ac.uk
2. Mr Phil Toozs-Hobson (scientific)

Study website
http://www.birmingham.ac.uk/C-Stich

Contact information

Type(s)
Public

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Type(s)
Scientific

Contact name
Mr Phil Toozs-Hobson

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United Kingdom
B15 2TG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.birmingham.ac.uk/Documents/college-mds/trials/bctu/C-stich/C-STICH-PIS-V4.0-23-Mar-2017-clean.doc

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 measure
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

Secondary outcome measures
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)
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.

Overall study start date
01/03/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2050

Total final enrolment
2051

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
England

Scotland

United Kingdom

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

Sponsor details
Birmingham Women's NHS Foundation Trust
Norton Court
Mindelsohn Way
Edgbaston
Birmingham
England
United Kingdom
B15 2TG

Sponsor type
Hospital/treatment centre

Website
http://www.bwnft.nhs.uk/research-developments

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

Publication and dissemination plan
A meeting will be held after the end of the study to allow discussion of the main results among the collaborators prior to publication. The success of the study depends entirely on the wholehearted collaboration of a large number of doctors, nurses and others. For this reason, chief credit for the main results will be given not to the committees or central organisers but to all those who have collaborated in the study. Centres will be permitted to publish data obtained from participants in the C-STICH trial that use trial outcome measures but do not relate to the trial randomised evaluation and hypothesis.

Intention to publish date
31/01/2022

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?
Protocol article	protocol	28/09/2021	30/09/2021	Yes	No
Results article		22/10/2022	24/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2024	10/09/2024	Yes	No