

Cerclage Outcome by the Type of Suture material (COTS) study

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| Submission date 04/02/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 27/03/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 22/10/2018 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

The COTS study addresses a research question which could potentially save the lives of more than 400 babies per year in the UK alone. These babies would otherwise die because of severe prematurity or early pregnancy loss. Undoubtedly, the improved outcome will have significant psychosocial benefits and health resource implications. Laxity (weakness) of the neck of the womb (cervix) is one of the main causes of premature birth and early pregnancy loss for which a suture around the cervix (cerclage) has been used for many years. It is estimated that 6700 women will have a cerclage in the UK per year with varying success rates. Braided sutures have been traditionally used because they are deemed to be strong and easy to remove. However, braided non-dissolvable sutures have been consistently associated with increased risk of infection in most surgical procedures and are no longer used in eye and pelvic surgery for that reason. Infection is a major contributing factor to cerclage failure. Hence, some surgeons prefer to use monofilament non-braided sutures in cerclage. However, there is perceived concern about the degree of cervical support such sutures offer. We conducted a national survey of UK-based consultants Obstetricians & Gynaecologists which demonstrated that the majority of doctors were uncertain which is the best suture material for their patients. Therefore, COTS pilot study will provide the necessary information to confidently inform the need for a large national multi-centre study.

Who can participate?

All women (>17 years) with a singleton pregnancy and a valid indication for cervical cerclage:

- History of three or more previous mid trimester losses or premature (<28 weeks) births.
- Had cervical sutures in previous pregnancies
- History of mid-trimester loss or premature delivery with a shortened cervix on ultrasound scan (<25mm).
- Deemed at risk of preterm labour at the clinicians discretion (e.g. radical trachelectomy)

What does the study involve?

Eligible women will be randomly allocated to undergo cerclage either using a braided (standard) or non-braided (test material) suture between 14-20 weeks gestation. Apart from the type of

suture material, participants will receive identical treatment. Outcomes to be measured are live birth rate, gestational age at birth, infection risk, mode and timing of delivery, length of hospital, any injuries to the cervix and neonatal unit stay.

What are the possible benefits and risks of participating?

There are no direct benefits to participants. The information we get from this study will help us to identify which suture is best to be used for the cerclage (stitch round the cervix) and is the best for prolongation of pregnancy.

There are no additional risks associated with taking part in this research. The risks of any cerclage are described below. Both stitches are commonly used and have theoretical advantage in preventing preterm labour or mid trimester loss. Inserting cervical stitch is a relatively common procedure. However, there are always risks to any surgical procedure. The uncommon risks (occurs in 1 out of 100-1000) include bleeding, infection and pain. It is usual to experience some period like tummy pain afterwards. We can give you some painkillers if necessary. You may also have some slight vaginal bleeding. This should stop within a few days. If you have increased vaginal discharge and your doctor worried about the infection, you may have vaginal swab taken. If there is evidence of infection you may be prescribed antibiotics.

There is no evidence that abstinence from sex following cerclage insertion has any impact on preterm delivery. It is also not routinely recommended to get a complete bed rest after the procedure. In a very small number of cases there is a technical difficulty with the procedure, so it may result in miscarriage or rupture of membranes. This is not, as far as we are aware, related to the suture material. The risk of premature delivery of the baby remains throughout the pregnancy (but this is the reason for the stitch).

Where is the study run from?

Several Units in Birmingham and one unit in Cambridge.

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

Study started in February 2013 and expected to run for 18 months.

Who is funding the study?

This pilot/feasibility study is funded by Urogynae Research Fund at Birmingham Womens Hospital

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A pilot/feasibility RCT comparing monofilament (intervention) versus multifilament (control) suture material for elective cervical cerclage in the management of suspected cervical incompetence

Acronym

COTS

Study objectives

COTS will address the following research question:

Is it feasible to conduct a definitive randomised controlled trial (RCT) evaluating the therapeutic effectiveness of monofilament/non-braided suture material versus multifilament &/or braided suture material in improving pregnancy outcomes following cervical cerclage procedure?

The research hypothesis for COTS is based on the evidence showing that multifilament / braided non-absorbable sutures are associated with a higher risk of infection and hence have been abandoned in several surgical disciplines.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands Research Ethics Committee, 11/06/2012, REC ref: 12/WM/0141

Study design

Multicentre pilot / feasibility 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 in web format, please contact Dr Fidan Israfil-Bayli, Birmingham Womens Foundation Trust, 3rd floor, Edgbaston, Birmingham, B15 2TG to request a patient information sheet

Health condition(s) or problem(s) studied

Midtrimester miscarriage or preterm birth due to cervical incompetence

Interventions

Cerclage can occur at any gestation between 14-20 weeks as long as it is performed as an elective procedure. The Monofilament non-braided suture used will be a looped Nylon and the Multifilament braided suture will be Mersilene tape for the intervention and control groups respectively. The stitch will be inserted using a McDonald technique. Planned removal of the suture would occur at 37 (+/-1 week) weeks gestation. When the stitch is removed it will be retained for microbiological investigations. A vaginal swab will be taken before the cerclage procedure to ensure that any infection is treated before inserting the suture. A vaginal swab will also be taken at the time of suture removal. The follow up should not involve additional contact with the patient beyond routine local clinical management protocols. Data required for all the proposed outcomes are significant objective outcomes in patient care and will be collected by notes review other than those required in the qualitative interviews. The study will be deemed complete when the last recruited woman has delivered and, if applicable, her baby is discharged from the neonatal unit.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Live birth rate

Secondary outcome measures

1. Gestation at delivery
2. Mode of delivery
3. Length of stay in neonatal unit

Overall study start date

06/02/2013

Completion date

08/02/2014

Eligibility

Key inclusion criteria

1. All women (>17 years) with a singleton pregnancy and a valid indication for cervical cerclage, as per Royal College of Obstetricians and Gynaecologists (RCOG) guidance, as follows:

- 1.1. History of three or more previous mid trimester losses or premature (<28 weeks) births.
- 1.2. Had cervical sutures in previous pregnancies
- 1.3. History of mid-trimester loss or premature delivery with a shortened cervix on ultrasound scan (<25mm)
- 1.4. Deemed at risk of preterm labour at the clinicians discretion (e.g. radical trachelectomy)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

100

Key exclusion criteria

1. Women who are unable or unwilling to give informed consent
2. Multiple pregnancy
3. Women under the age of 17 years

Date of first enrolment

06/02/2013

Date of final enrolment

08/02/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Birmingham Women's Hospital

Birmingham

United Kingdom

B5 2TG

Sponsor information

Organisation

Birmingham Women's Hospital (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://bwhct.nhs.uk>

ROR

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

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Birmingham Women's Hospital (UK) - Urogynaecology Research Fund

Funder Name

Birmingham Clinical Trials Unit (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 27/10/2014 | | Yes | No |