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

Submission date
04/02/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
22/10/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 (weakeness) 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

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Additional identifiers

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

Primary study design
Interventional

Study design
Multicentre pilot / feasibility randomised controlled trial

Study type(s)
Treatment

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(s)
Live birth rate

Key secondary outcome(s)
1. Gestation at delivery
2. Mode of delivery
3. Length of stay in neonatal unit

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B5 2TG

Sponsor information

Organisation
Birmingham Women's Hospital (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

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