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A randomised trial in women with a twin pregnancy, using the Arabin pessary to prevent preterm birth – STOPPIT-2

Submission date
05/11/2014

Recruitment status
No longer recruiting

Registration date
03/12/2014

Overall study status
Completed

Last Edited
06/07/2021

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
This study aims to confirm whether the Arabin cervical pessary prevents preterm birth in women with a twin pregnancy and a short cervix (neck of the womb). Preterm birth is associated with increased risk of death and ill health for the baby, so if preterm birth could be prevented in twins this would be a very good thing. The Arabin cervical pessary is used to reduce preterm birth in women with a singleton pregnancy (one baby). A Dutch study has suggested that the cervical pessary might also prevent preterm birth in twins. Although the pessary did not work in all twins, it appeared to reduce preterm birth in those women with a twin pregnancy who had a short cervix. The study aims to resolve uncertainty around whether the Arabin pessary reduces spontaneous preterm birth in twins and improves outcomes for babies, and whether women find the treatment acceptable. It will also calculate the costs for the NHS. We will look at the proportion of babies who are born before 34 weeks and the complications that happen to babies, and we will compare these between the two groups.

Who can participate?
Women aged 16 or older with a twin pregnancy, ≤16 weeks gestation

What does the study involve?
We will ask around 2500 women if they will have an ultrasound scan to measure their cervix usually around the same time as they have a fetal anomaly scan. Women who are in the lowest 30% of cervical length measurements (around 500) will be asked if they want to join the treatment phase of the study. Those who agree will be randomly allocated to be treated with either the Arabin pessary or standard treatment. The pessary will be inserted between the beginnings of the 18th to the end of the 20th week of pregnancy, and then removed at 36 weeks. We will collect information about women and their babies' delivery details and well-being postnatally.

What are the possible benefits and risks of participating?
There is evidence that the Arabin pessary helps prevent preterm birth. However, we cannot promise the study will directly help you or your babies. The information we obtain from your participation in the study may help inform the future healthcare of other patients.

Where is the study run from?
Simpson Centre for Reproductive Health (UK)

When is the study starting and how long is it expected to run for?
October 2014 to July 2019

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02235181

Secondary identifying numbers
17820; HTA 13/04/22

Study information

Scientific Title
An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability - STOPPIT-2

Acronym
STOPPIT--2

Study objectives
This study aims to confirm whether the Arabin cervical pessary prevents preterm birth in women with a twin pregnancy and a short cervix. Preterm birth is associated with increased risk of death and ill health for the baby, so if preterm birth could be prevented in twins this would be a very good thing. The Arabin cervical pessary is used to reduce preterm birth in women with a singleton pregnancy (one baby). A Dutch study which finished late last year has suggested that the cervical pessary might also prevent preterm birth in twins. Although the pessary did not work in all twins, it appeared to reduce preterm birth in those women with a twin pregnancy who had a short cervix (neck of the womb).

The study we propose here will resolve uncertainty around whether the Arabin pessary reduces spontaneous preterm birth in twins and improves outcomes for babies, define any adverse effects for mother and baby, ascertain whether women find the treatment acceptable and will calculate the costs for the NHS.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/130422

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland 02, 14/SS/1031

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
In a large number of NHS centres, we will ask around 2500 women with a twin pregnancy if they will have an ultrasound scan to measure their cervix around the same time as they have a fetal anomaly scan. Women who are in the lowest 30% of cervical length measurements (around 500) will be asked if they want to join the treatment phase of the study. Those who agree will be treated with either the Arabin pessary or standard treatment. The pessary will be inserted between the beginning of the 18th to the end of the 20th week of pregnancy, and then removed at 36 weeks. The Arabin pessary will be inserted by a clinician who has completed the online training. We will look at the proportion of babies who are born before 34 weeks and the complications that happen to babies and we will compare these between the two groups. We will also perform an economic analysis to determine the cost-effectiveness of the Arabin pessary, and ask women about their experience of using the pessary.

Cervical length will be measured by someone who has completed the Fetal Medicine Foundation or CLEAR accreditation for cervical length measurement. This will normally take place in the ultrasound department, often at the time of routine fetal anomaly scanning.

Intervention Type
Other

Primary outcome measure
1. Does the Arabin cervical pessary reduces spontaneous preterm labour (< 34 weeks) leading to preterm birth; time frame: delivery of the babies
2. Neonatal outcomes; time frame: within 4 weeks after expected date of delivery

Secondary outcome measures
1. The profile of cervical length measurements in women with twin pregnancy in the UK; time frame: 18-20 weeks gestation
2. Participant satisfaction using a validated questionnaire; time frame: 36 weeks gestation -

updated 06/04/2018: 30 and 36 weeks gestation
3. Health economics using a questionnaire and data collected from medical notes; time frame: 18-20 weeks gestation until 4 weeks postnatal

Overall study start date
30/10/2014

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Women presenting with twin pregnancy (monochorionic or dichorionic)
2. Women with gestation established by scan at ≤16 weeks according to NICE guidelines
3. Women aged 16 years or older
4. Women wishing to participate in both the screening and treatment phase of the study
Target Gender: Female; Upper Age Limit 50 years; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 2500; UK Sample Size: 2500

Total final enrolment
2228

Key exclusion criteria
Screening phase:
1. Women unable to give written informed consent
2. Women with known significant congenital structural or chromosomal fetal anomaly at the time of inclusion
3. Women with existing or planned cervical cerclage in the current pregnancy
4. Women with existing or planned (prior to 20+6 weeks gestation) treatment for twin-to-twin transfusion syndrome in the current pregnancy
5. Women with suspected or proven rupture of the fetal membranes at the time of recruitment
6. Women with singleton pregnancy or higher order multiple pregnancies
7. Women with known sensitivity, contraindication or intolerance to silicone
8. Women involved in a clinical trial of an investigational medicinal product (CTIMP)

Treatment phase:
1. Women with a cervical length > 30 mm at 18+0 20+6 weeks gestation - updated 06/04/2018: women with a cervical length > 35 mm at 18+0 20+6 weeks gestation

Date of first enrolment
01/04/2015

Date of final enrolment
14/02/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Simpson Centre for Reproductive Health
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh

Sponsor details
QMRI
51 Little France Crescent
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Sponsor type
University/education

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

Sponsor details
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
United Kingdom
EH1 3EG
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R&DOffice@nhslothian.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhslothian.scot.nhs.uk/Pages/default.aspx

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The current Protocol/SAP/PIS/Consent are available on the project website: https://w3.abdn.ac.uk/hsru/stoppit2/Public/DownloadPage.aspx

The clinical study report will be used for publication and presentation at scientific meetings. The results of the study and any protocol deviations will be published in writing by a team headed by the Chief Investigator, which will report to the Trial Steering Committee. Individual investigators may be able to produce oral reports with the permission of the Project Management Group. Summaries of results will also be made available to Investigators for dissemination within their clinics (where appropriate and according to their discretion).

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Jane E Norman (Jane.Norman@ed.ac.uk). Anonymised data will be shared when it becomes available after study publication and for a least 5 years after the end of trial. Consent for use in future studies was obtained as per GDPR.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/12/2018		Yes	No
Abstract results	abstract	01/01/2020	07/07/2020	No	No
Results article		29/03/2021	30/03/2021	Yes	No
Results article		01/07/2021	06/07/2021	Yes	No
HRA research summary			28/06/2023	No	No