ISRCTN98835694 https://doi.org/10.1186/ISRCTN98835694

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?
Sonia Whyte
sonia.whyte@ed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Sonia Whyte

Contact details
Room S7129
Simpson Centre for Reproductive Health
Royal Infirmary
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Type(s)
Scientific

Contact name
Prof Jane E Norman

ORCID ID
https://orcid.org/0000-0001-6031-6953

Contact details
University of Edinburgh MRC Centre for Reproductive Health
Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TY

+ 44 (0)131 242 2694
jane.norman@ed.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02235181

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)

Prevention

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

Scotland

Study participating centre

Simpson Centre for Reproductive Health
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

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 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?
Results article		29/03/2021	30/03/2021	Yes	No
Results article		01/07/2021	06/07/2021	Yes	No
Protocol article	protocol	06/12/2018		Yes	No
Abstract results	abstract	01/01/2020	07/07/2020	No	No
HRA research summary			28/06/2023	No	No