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Prevention of preterm birth

Submission date
09/03/2016

Recruitment status
No longer recruiting

Registration date
10/03/2016

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
About 11% of all babies born worldwide are preterm (premature), meaning that they are born more than three weeks before their due date. The earlier babies are born, the more likely they are to die or develop long-term complications of brain, lung and gut development, particularly those born before 32 weeks. Prematurity is a huge emotional burden for families and communities, and a financial burden costing the public sector an extra £2.95 billion annually. Two-thirds of preterm births (PTB) happen spontaneously, the reason for which is unclear. Women who have previously had a PTB, have had important tissue removed from their cervix (neck of womb), or have a short cervix are more likely to give birth prematurely than the general population. There are currently three main treatments available which aim to help prolong pregnancy, preventing PTB: an arabin pessary, a cervical cerclage, or a vaginal progesterone pessary. It is currently not known which technique is the most effective. The aim of this study is to compare these treatments in a small study in order to find out whether it would be possible to later conduct a large-scale study.

Who can participate?
Women aged 18 and over who are between 16 and 24 weeks pregnant with a single baby, who are at risk of having a pre-term birth.

What does the study involve?
Participants are randomly allocated to receive one of three treatments: an arabin pessary (a silicone cup inserted vaginally to support the pregnancy), a cervical cerclage (a stitch placed surgically into the cervix), or a vaginal progesterone pessary (a vaginal tablet containing the hormone progesterone that is put in place by the patient every night). Patient and staff acceptability is measured 1-2 months after the end of the study, and the feasibility of recruiting participants for a large-scale study is assessed at 12 months after recruitment, along with an economic analysis.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
October 2015 to August 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Christine Cornforth (scientific)
2. Mrs Ediri O'Brien (public)

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-003112-36

Protocol serial number

18675

Study information

Scientific Title
Three-arm randomised trial of cervical cerclage, arabin pessary and vaginal progesterone to prevent spontaneous preterm birth in asymptomatic women at high-risk of preterm birth: A feasibility study

Study objectives
The aim of this study is to explore the feasibility of recruiting participants for a large-scale clinical trial looking at different treatments designed to prevent preterm labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NW/1392

Primary study design
Interventional

Study design
Three-arm multi-centre randomised parallel trial

Study type(s)
Treatment

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

Interventions
Participants are randomly allocated to receive one of three treatments:
1. Arabin pessary: silicone cerclage pessary device sited around cervix in clinic
2. Cervical cerclage: Macdonald technique to site suture, surgically in cervical tissue. Performed in theatre under aseptic technique
3. Vaginal progesterone: single administration vaginal micronised progesterone pessary (Uterogestan) 200mg nocte pv, prescription given in clinic and collected from pharmacy

Intervention Type
Mixed

Primary outcome(s)
Feasibility is measured at 12 months post recruitment, with follow up until final mother and baby discharge or 6 weeks postnatal.

Key secondary outcome(s)
1. Economic analysis is completed at 12 months post recruitment
2. Patient and staff acceptability is measured 1-2 months post study completion

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Singleton pregnancy
3. Between 16+0 – 24+6 weeks in current pregnancy
4. History of previous spontaneous preterm birth (sPTB) or premature rupture of membranes (PPROM) between 16-33+6
AND
5. Cervical length at least <3rd centile for gestational age
OR
6. History of significant cervical surgery defined as two large loop excision of the transformation zone (LLETZ) procedures or a single knife cone biopsy (KCB) where a clinical decision is made to treat the short cervix
7. Clinical equipoise as to what is the best treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Known or suspected structural or chromosomal fetal abnormality
2. Inability to give informed consent
3. Treatment with history indicated cerclage
4. Treatment with vaginal progesterone within two weeks of randomisation
5. All contraindications to use of progesterone (see protocol 6.2)

Date of first enrolment
06/10/2015

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cancer Research UK Liverpool Cancer Trials Unit
University of Liverpool
1st floor Block C
Waterhouse Building
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Sponsor information

Organisation
University of Liverpool (UK)

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

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?
HRA research summary			28/06/2023	No	No