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A multicentre randomised controlled trial of transabdominal versus transvaginal cervical cerclage

Submission date
29/08/2008

Recruitment status
No longer recruiting

Registration date
26/09/2008

Overall study status
Completed

Last Edited
06/05/2020

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol 1

Study information

Scientific Title
A multicentre randomised controlled trial of transabdominal versus transvaginal cervical cerclage

Acronym
MAVRIC - Multicentre Abdominal vs Vaginal Randomised Investigation of Cerclage

Study objectives
A transbadominal or a high vaginal cerclage will be associated with a lower rate of preterm birth (<32 weeks) and neonatal death than a low vaginal cerclage in women who have had a second trimester loss or early preterm birth (<28 weeks) despite having a low vaginal cerclage in situ.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 20/11/2007, ref: 07/H1102/113

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Preterm birth - prevention

Interventions
The participants will be randomly allocated to the following three arms:
1. Low vaginal cervical cerclage
2. High vaginal cervical cerclage
3. Transabdominal cervical cerclage

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Rate of delivery <32 weeks' gestation
2. Rate of neonatal death

Key secondary outcome(s))
1. Serious operative complication rates
2. Complications of pre- and post-conception cerclages for high vaginal cerclages and transabdominal cerclages

Duration of follow up: a maximum of 2 years

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Previous second trimester miscarriage or preterm birth before 28 weeks' gestation despite having a low vaginal cerclage in place
2. Not yet pregnant or <14 weeks' pregnant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
111

Key exclusion criteria
1. Inability or unwillingness to give informed consent
2. Women under the age of 16

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Moulton Charitable Foundation (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?
Results article	results	01/03/2020	06/05/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes