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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

Study website
http://www.medscinet.net/mavric/

Contact information

Type(s)
Scientific

Contact name
Prof Andrew Shennan

Contact details
King's College London
Division of Reproduction & Endocrinology
Maternal and Foetal Research Unit
10th Floor North Wing
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)207 188 3639
andrew.shennan@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Patient information can be found at: http://www.medscinet.net/mavric/patientinfodocs/PIS_221107[1].doc

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 measure
1. Rate of delivery <32 weeks' gestation
2. Rate of neonatal death

Secondary outcome measures
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

Overall study start date
01/01/2008

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

Age group
Adult

Sex
Female

Target number of participants
129

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
England

United Kingdom

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

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Keith Brennan
Assistant Head of Administration (Health)
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL
+44 (0)207 848 6960
keith.brennan@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Moulton Charitable Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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