

A multicentre randomised controlled trial of transabdominal versus transvaginal cervical cerclage

Submission date

29/08/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

26/09/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

06/05/2020

Condition category

Pregnancy and Childbirth

☐ 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](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