

A multicentre randomised controlled trial of transabdominal versus transvaginal cervical cerclage

Submission date 29/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 transabdominal 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