

Randomised study of pessary vs standard management in women with increased chance of premature birth

Submission date 05/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/03/2020	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

ClinicalTrials.gov (NCT)
NCT00735137

Protocol serial number
07WH10

Study information

Scientific Title

Randomised study of pessary vs standard management in women with increased chance of premature birth

Study objectives

Current hypothesis as of 12/08/2008:

Is pessary useful in reducing risk of premature birth in women with singleton pregnancies with a short cervix (cervical length of 25 mm or less at 21-24 weeks) or in twin pregnancies?

Previous hypothesis:

Is pessary useful in reducing the risk of premature birth in twin pregnancy?

Ethics approval required

Old ethics approval format

Ethics approval(s)

King's College Hospital Research Ethics Committee, 31/01/2008, ref: 08/H0808/3

Primary study design

Interventional

Study design

Multi-centre randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Premature birth in women with increased risk of premature birth

Interventions

Treatment with insertion of vaginal pessary vs expectant management. The vaginal pessary is inserted in those allocated to this group within 5 days after the 20-24+6 weeks scan. The pessary will be removed by a simple vaginal examination before delivery.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Spontaneous delivery before 34 weeks of gestation

Key secondary outcome(s)

1. Birth weight (mean, less than 2.5 kg and less than 1.5 kg)
2. Foetal or neonatal death
3. Major adverse outcomes before discharge from the hospital (intraventricular haemorrhage, respiratory distress syndrome, retinopathy of prematurity or necrotising enterocolitis)

4. Need for neonatal special care (admission to a neonatal intensive care unit, ventilation, phototherapy, treatment for proven or suspected sepsis or blood transfusion). Duration of follow-up: 2 years

Completion date

15/04/2012

Eligibility**Key inclusion criteria**

Current inclusion criteria as of 12/08/2008:

1. Women with singleton pregnancies and with a cervical length of 25 mm or less
2. Women with twin pregnancies

Previous inclusion criteria:

1. Women with twin pregnancies undergoing routine ultrasonography at 20-24+6 weeks of gestation for examination of foetal anatomy and growth
2. Both foetuses are found to be alive with no major abnormalities, severe twin to twin transfusion syndrome or severe foetal growth restriction

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Current exclusion criteria as of 12/08/2008:

1. Major foetal abnormalities (defined as those that are lethal or require prenatal or postnatal surgery), foetal death, severe twin to twin transfusion syndrome or severe foetal growth restriction in one of the foetuses (in the case of twin pregnancy) diagnosed before randomisation
 2. Painful regular uterine contractions, history of ruptured membranes, or prophylactic cerclage before randomisation
 3. Patients who are unconscious, severely ill, mentally handicapped or under the age of 16 years
- Previous exclusion criteria:

1. Major foetal abnormalities (defined as those that are lethal or require prenatal or postnatal surgery), or death of one or both of the foetuses, severe twin to twin transfusion syndrome diagnosed before randomisation
2. Painful regular uterine contractions, history of ruptured membranes, or prophylactic cerclage before randomisation
3. Patients who are unconscious, severely ill or mentally handicapped
4. Under the age of 16 years

Date of first enrolment

15/04/2008

Date of final enrolment

15/04/2012

Locations

Countries of recruitment

United Kingdom

England

Brazil

Chile

Colombia

Portugal

Spain

Study participating centre

King's College Hospital

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King's College Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/01n0k5m85>

Funder(s)

Funder type

Charity

Funder Name

Fetal Medicine Foundation (UK)

Alternative Name(s)

FMF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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?
Results article	results	01/01/2016		Yes	No
Results article	results	17/03/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes