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# 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

**Registration date**
28/05/2008

**Overall study status**
Completed

**Last Edited**
13/03/2020

**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

**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

## Study design
Multi-centre randomised controlled trial

## Primary study design
Interventional

## 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 entercolitis)

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 |