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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00735137

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Patient information sheet for women with singleton pregnancies can be found at http://www.fetalmedicine.com/research/prem-single-info.htm. Patient information sheet for women with twin pregnancies can be found at http://www.fetalmedicine.com/research/prem-twins-info.htm.

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 measure
Spontaneous delivery before 34 weeks of gestation

Secondary outcome measures
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

Overall study start date
15/04/2008

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

Age group
Adult

Sex
Female

Target number of participants
2,780 (1,180 twin pregnancies and 1,600 singleton pregnancies)

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
Brazil

Chile

Colombia

England

Portugal

Spain

United Kingdom

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Directorate of Research and Development
King's College Hospital
Denmark Hill
London
England
United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.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

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	01/01/2016		Yes	No
Results article	results	17/03/2016		Yes	No