ISRCTN61066532 https://doi.org/10.1186/ISRCTN61066532

Randomised trial of cervical cerclage in women with a short cervix identified by routine sonography at 23 weeks of pregnancy

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
02/12/2008

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

Secondary identifying numbers
REC00302

Study information

Scientific Title

Study objectives
Objectives: to measure the possible benefit of cervical cerclage in women with a very short cervix identified during routine sonographic assessment of cervical length at 23 weeks of gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and childbirth: Pregnancy

Interventions
Randomised to cervical cerclage or to expectant management

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Spontaneous pre-term delivery at less than or equal to 32 weeks in the two groups

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/12/1998

Completion date
01/12/2000

Eligibility

Key inclusion criteria
Women with singleton pregnancies attending for routine antenatal care at King's College Hospital.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
250

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/1998

Date of final enrolment
01/12/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
London
United Kingdom
SE5 8RX

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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	05/06/2004		Yes	No