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

Submission date Recruitment status [ ] Prospectively registered 23/01/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [ ] Individual participant data Last Edited Condition category Pregnancy and Childbirth 02/12/2008

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Kypros Nicolaides

#### Contact details

King's College Hospital
Harris Birthright Research Centre for Fetal Medicine
Denmark Hill
London
United Kingdom
SE5 8RX
+44 020 7346 3040

## 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              |