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The CIRCLE Trial - Cerclage in Relation to Cervical LEngth. A clinical study to determine the effects of cervical scanning and cervical stitches in preventing preterm labour

Submission date
05/10/2004

Recruitment status
No longer recruiting

Registration date
17/01/2005

Overall study status
Completed

Last Edited
07/04/2015

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

Protocol serial number
RJ1 04/0199

Study information

Scientific Title
The CIRCLE Trial - Cerclage in Relation to Cervical LEngth.
A clinical study to determine the effects of cervical scanning and cervical stitches in preventing preterm labour

Acronym
CIRCLE

Study objectives
Not provided at time of registration

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

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Preterm labour

Interventions
Intervention group: Therapeutic cervical suture if cervical canal shortens to ≤20 mm
Control group: Elective cervical suture will only be inserted if the past obstetric history is suggestive of cervical incompetence

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/11/2008

Eligibility

Key inclusion criteria
Pregnant women at high risk of preterm labour.
Eligibility criteria: any pregnant woman, with a singleton pregnancy, between 16-24 weeks of pregnancy, with a history of one or more previous spontaneous deliveries prior to 34 weeks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2003

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Tommy's Baby Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/06/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes