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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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

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

Age group
Adult

Sex
Female

Target number of participants
1890

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
England

United Kingdom

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

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Research and Development
Ground Floor, West Wing
Counting House, Guys Hospital
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Sponsor type
Hospital/treatment centre

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

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	01/06/2009		Yes	No