

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	<input type="checkbox"/> Prospectively registered
Registration date 17/01/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

London

England

United Kingdom

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+44 (0)207 188 5731

Jeff.Brazel@gstt.sthames.nhs.uk

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