

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

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