ISRCTN59759835 https://doi.org/10.1186/ISRCTN59759835

Randomised trial of intrapartum tractocile versus placebo in the management of fetal distress in women undergoing emergency Caesarean section

Submission date
12/09/2003

Recruitment status
Stopped

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
05/10/2011

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N0059103677

Study information

Scientific Title

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Fetal distress

Interventions
Intrapartum tractocile versus placebo.

Added June 2008: trial abandoned and never recruited patients.

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
01/03/2004

Completion date
28/02/2006

Reason abandoned (if study stopped)
Lack of resources

Eligibility

Key inclusion criteria
Women undergoing emergency Caesarean section.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Recruitment target: 240

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2004

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

STH NHS Trust
Sheffield
United Kingdom
S10 2SF

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Sheffield Teaching Hospitals (Central Campus) - 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