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

Submission date 12/09/2003	<b>Recruitment status</b> Stopped	[X] Prospectively registered [] Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	Results
Last Edited	Condition category	[] Individual participant data
05/10/2011	Pregnancy and Childbirth	[] Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

#### **Contact information**

### Type(s)

Scientific

#### Contact name

Dr Tom Farrell

#### **Contact details**

STH NHS Trust OGN & Midwifery Jessop Wing Sheffield United Kingdom S10 2SF +44 (0)114 226 8163 tom.farrell@sth.nhs.uk

### 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