

# Randomised, double-blinded placebo controlled trial of the use of tocolysis for a repeat external cephalic version after a failed version for breech presentation at term

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2010	<b>Condition category</b> 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

SEO093

## Study information

Scientific Title

### Study objectives

To determine the optimum protocol for performing external cephalic version for breech presentation at term. Null hypothesis: that tocolysis for a repeat external cephalic version (ECV) after a failed ECV does not increase the success rates of ECV

### 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)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Childbirth

### Interventions

1. 50 mg ritodrine hydrochloride infusion
2. 17 ml dextrose saline solution infusion

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

1. Incidence of cephalic presentation at delivery
2. Subjective patient assessment of discomfort
3. Incidence of caesarian section
4. Length of hospital stay
5. Incidence of neonatal Apgar scores <7 at 5 minutes
6. Incidence of neonatal intensive care admission

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

06/04/2000

**Completion date**

06/04/2002

**Eligibility****Key inclusion criteria**

1. Women with suspected or confirmed breech presentation at >36 weeks gestation
2. Have undergone a single (<15 mins) unsuccessful attempt at external cephalic version without tocolysis at 37 or more weeks' gestation

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

124 (added 12/01/10, see publication)

**Key exclusion criteria**

1. Abnormal cardiotocograph
2. Cardiac disease
3. Pre-existing or gestational diabetes
4. Hypertension;
5. Pre-existing indication for caesarian section
6. Suspected unstable lie
7. Pre-eclampsia
8. recent (<4 weeks) antepartum haemorrhage
9. suspected fetal compromise
10. rhesus immunisation

**Date of first enrolment**

06/04/2000

**Date of final enrolment**

06/04/2002

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Level 4**

Oxford

United Kingdom

OX3 9DU

## **Sponsor information**

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NHS Executive South East (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2005		Yes	No