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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

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
12/01/2010

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Lawrence Impey

Contact details
Level 4
The Women's Centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865741166 Ex 21408/21624
LWMI@compuserve.com

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?
Results article	results	01/05/2005		Yes	No