

External cephalic version trial

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/08/2008	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

Study website

<http://www.stuitonderzoek.nl>

Contact information

Type(s)

Scientific

Contact name

Dr M. Kok

Contact details

Academic Medical Centre
Department of Obstetrics and Gynaecology
H4-205, Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 5664167
mkok@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR140

Study information

Scientific Title

Management of breech presentation - external cephalic version with tocolysis: a multicentre randomised controlled trial

Study objectives

For women with a singleton at term foetus in breech presentation, what is the success rate of external cephalic version (ECV) with a calcium antagonist nifedipine compared to version without medication?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from local ethics committee

Study design

Multicentre, randomised, double blind, placebo controlled parallel group 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

Breech presentation

Interventions

Group 1: external cephalic version with tocolysis (adalat 10 mg orally 30 and 15 minutes before procedure)

Group 2: external cephalic version without tocolysis.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tocolysis

Primary outcome measure

Successful version.

Secondary outcome measures

1. Cephalic presentation at birth
2. Caesarean section rate
3. Foetal complications
4. Maternal complications

Overall study start date

01/08/2004

Completion date

01/05/2006

Eligibility

Key inclusion criteria

Pregnant women (from 18 years of age) with a live singleton at term foetus in breech presentation.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

300

Key exclusion criteria

1. Contraindications to labour or vaginal birth
2. Any contraindication to ECV
3. Contraindications for nifedipine

Date of first enrolment

01/08/2004

Date of final enrolment

01/05/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

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	01/08/2008		Yes	No