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External cephalic version trial

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/08/2008	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.stuitonderzoek.nl

Contact information

Type(s)
Scientific

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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