ISRCTN28715121 https://doi.org/10.1186/ISRCTN28715121

External cephalic version trial

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
04/08/2008

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Successful version.

Key secondary outcome(s))
1. Cephalic presentation at birth
2. Caesarean section rate
3. Foetal complications
4. Maternal complications

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes