External cephalic version trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22775

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Breech presentation.

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: Academic Medical Centre

Intervention

Outcome measures

Primary outcome

Succesfull version.

Secondary outcome

1. Cephalic presentation at birth;

2. Caesarean section rate;

3. Fetal complications;

4. Maternal complications.

Study description

Background summary

External cephalic version (ECV) without tocolysis after 36 weeks of gestation can reduce the breech presentation by 41%. ECV with tocolysis is more successful and has a success rate of 57%.

Currently used tocolytics have maternal cardiovascular side-effects in terms of flushing and palpitations and therefore seldom used in clinical practice. A new tocolytic nifedipine, a calcium antagonist exists wich has significant less side effects(5).

Therefore, the goal of this trial is to asses for women with a singleton at term fetus in breech presentation the success rate of external cephalic version (ECV) with a calcium antagonist nifedipine compared to version without medication?

Study objective

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

Study design

N/A

Intervention

Group 1:

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

Group 2:

external cephalic version without tocolysis.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Contraindications to labour or vaginal birth, any contraindication to ECV, contra-indications for nifedipine.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2004
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL109

Register	ID
NTR-old	NTR140
Other	: N/A
ISRCTN	ISRCTN28715121

Study results

Summary results
Obstet Gynecol. 2008 Aug;112(2 Pt 1):271-6.