External Cephalic Version with uterine-relaxation: atosiban versus fenoterol; a multi centre trial.

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For women with a singleton fetus in breech presentation at term, this study answers the question if atosiban is more effective compared to fenoterol as a tocolyticum in external cephalic version

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON34006

Source
ToetsingOnline

Brief title
ECV; atosiban vs fenoterol

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Breech presentation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Onderzoeksgeld van de projectleider die het onderzoek uitvoert.

Intervention

Keyword: Atosiban, Breech, External Cephalic Version, Fenoterol

Outcome measures

Primary outcome

The primary outcome is a fetus being in cephalic position immediately after the procedure.

Secondary outcome

Secondary outcome measures include cephalic presentation at delivery, mode of delivery, side effects and adverse events.

Study description

Background summary

External cephalic version (ECV) of the fetus in breech position is a safe and relatively simple obstetrical intervention that reduces the incidence of caesarean section for breech position at term. Uterine relaxation can enhance the success rate of ECV significantly. The most studied and widespread used uterine relaxants are the beta-agonists, but these are not widely accepted in daily obstetrical practice because of cardiovascular side effects.
Nifedipine (a calcium channel blocker) and atosiban (an oxytocin-receptor antagonist) have been proven successful as tocolytics in preventing preterm labour and have replaced beta-agonists. Studies evaluating nifedipine or atosiban reported significantly less drop outs because of adverse drug reactions in comparison with beta-agonists. However, a RCT comparing nifedipine versus placebo for ECV could not show a significant difference on success rate.
This trial will compare the effectiveness of atosiban with fenoterol (beta-agonist) during ECV in women with a singleton fetus in breech presentation at term.

Study objective

For women with a singleton fetus in breech presentation at term, this study answers the question if atosiban is more effective compared to fenoterol as a tocolyticum in external cephalic version

Study design

The proposed design is an open label randomised controlled trial comparing atosiban with fenoterol as a tocolyticum during ECV. Patients assigned for randomisation will be stratified by centre and parity. This trial will be carried out by physicians and midwives who have experience in the ECV manoeuvre.

Intervention

One group receives 6.75 mg in 0.9 ml (7.5 mg/ml) atosiban i.v. and the other group receives a 40 microgram in 0.8 ml (0.5mg / 10 ml) fenoterol i.v. as a bolus.

Study burden and risks

There ar no other burden or risks for patients included in this study, compared to daily clinical practice for women with a singleton fetus in breech presentation at term.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Breech presentation

Exclusion criteria

Any contraindication to labour or vaginal birth (eg placenta praevia)

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	806
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Partusisten

Generic name:	Fenoterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	tractocile
Generic name:	atosiban
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-08-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2008-007344-34-NL
CCMO	NL26246.018.08