

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20784

### Source

NTR

### Brief title

ECV with uterine relaxation

### Health condition

stuitligging, uitwendige versie, uterus relaxatie, atosiban, oxytocine antagonist, fenoterol, betamimetica.

UK: breech presentation, external cephalic version, uterine relaxation, atosiban, oxytocine antagonist, fenoterol, betamimetics.

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC)

**Source(s) of monetary or material Support:** Academic Medical Center (AMC)

## Intervention

## Outcome measures

### Primary outcome

1. Successful version; number of cephalic presentations half an hour after the procedure;
2. Fetal presentation at delivery.

### **Secondary outcome**

1. Mode of delivery; vaginal delivery (spontaneous or instrumental), CS (prelabor or during labor);
2. Complications of ECV; persistent non-reassuring fetal CTG after ECV, umbilical cord prolapse, (P)PROM, placental abruption, emergency delivery, fetal death;
3. Adverse events due to atosiban or fenoterol; chest pain, nausea, vomiting, headaches, flushing, dizziness, hypotension (associated with fainting or CTG abnormalities), tachycardia resulting in palpitations, local reaction of the skin on injection of the medication, anaphylactic shock, cessation of treatment due to side effects.

## **Study description**

### **Background summary**

External cephalic version (ECV) is proven effective to reduce the number of caesarean sections in breech presentation at term. Until now, betamimetics are the only effective uterine relaxants; they increase the success rate of ECV by 40% and consequently lower the number of caesarean sections. Nevertheless, this medication has side effects which often leads to palpitations. Therefore, implementation of this treatment is limited. In this study, we compare fenoterol with atosiban to find out if atosiban is comparable to fenoterol in women with a breech presentation at term.

### **Study objective**

External cephalic version (ECV) of the fetus in breech position is a safe and relatively simple obstetric intervention to reduce the incidence of caesarean section for breech position at term. Uterine relaxants can enhance the success rate of ECV with 40%. Betamimetics (fenoterol) is proven effective as uterine relaxant in ECV, but has several side effects due to which it is not used on a daily basis. This trial will compare the effectiveness of atosiban with fenoterol during ECV in women with a singleton fetus in breech presentation at term.

### **Study design**

N/A

### **Intervention**

Comparison of a bolus atosiban 6,75 mg iv compared to a bolus 40 micrograms iv 15 minutes before ECV.

## Contacts

### **Public**

Academic Medical Center (AMC)  
Dept Gynaecology & Obstetrics, H4-140.1  
Meibergdreef 8

F. Vlemmix  
Academic Medical Center (AMC)  
Dept Gynaecology & Obstetrics, H4-140.1  
Meibergdreef 8

Amsterdam 1105AZ  
The Netherlands  
+31-(0)20-5666199

### **Scientific**

Academic Medical Center (AMC)  
Dept Gynaecology & Obstetrics, H4-140.1  
Meibergdreef 8

F. Vlemmix  
Academic Medical Center (AMC)  
Dept Gynaecology & Obstetrics, H4-140.1  
Meibergdreef 8

Amsterdam 1105AZ  
The Netherlands  
+31-(0)20-5666199

## Eligibility criteria

### **Inclusion criteria**

1. Pregnant women (from 18 years of age) with a live singleton fetus in breech presentation;
2. 32 weeks of gestation and onwards.

## Exclusion criteria

1. Contraindications to labour or vaginal birth;
2. Any contraindication to ECV;
3. Contra-indications for fenoterol or atosiban.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	806
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	25-06-2009
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	NL1767
NTR-old	NTR1877
Other	METC AMC : 26246
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A