# Nifedipine versus Atosiban in the treatment of threatened preterm labour: APOSTEL III

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To compare the effectiveness of the tocolytic agents Nifedipine (a calcium channel blocking agent) versus Atosiban (an oxytocin receptor antagonist) in the improvement of neonatal outcome in women with threatened preterm labour (25-34 weeks...

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

# Summary

## ID

NL-OMON38113

**Source** ToetsingOnline

Brief title APOSTEL III

# Condition

• Pregnancy, labour, delivery and postpartum conditions

#### **Synonym** Preterm delivery, threatened preterm birth

# Research involving

Human

# **Sponsors and support**

**Primary sponsor:** Academisch Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

1 - Nifedipine versus Atosiban in the treatment of threatened preterm labour: APOST ... 23-06-2025

## Intervention

Keyword: Premature delivery, Tocolysis

### **Outcome measures**

#### **Primary outcome**

The primary outcome of the study will be a composite for poor neonatal outcome. This outcome will include chronic lung disease, periventricular leucomalacia > grade 1, intraventricular haemorrhage > grade 2, NEC > stage 1, proven sepsis and in-hospital death.

#### Secondary outcome

Secondary outcomes will be time to delivery, gestational age at delivery,

number of days on ventilation support, number of days in NICU, total days of

the baby alive outside the hospital counted from a gestational age of 37 weeks

and maternal side effects.

# **Study description**

#### **Background summary**

Preterm labour is one of the most important obstetric problems throughout the Western world and occurs in approximately 10% of all deliveries. Preterm birth is the leading cause of perinatal mortality (70 %) and accounts for 40 % of severe neurological morbidity. Tocolysis is crucial in the treatment of threatened preterm labour, in order to allow for corticosteroids to exert their optimal effect on fetal lung development. The optimal tocolytic drug is subject to controversy.

#### **Study objective**

To compare the effectiveness of the tocolytic agents Nifedipine (a calcium channel blocking agent) versus Atosiban (an oxytocin receptor antagonist) in the improvement of neonatal outcome in women with threatened preterm labour (25-34 weeks gestation).

#### Study design

Multicenter randomized controlled trial

#### Intervention

Nifedipine (dosage: first hour 20 mg followed by 4 dd 20 mg retard orally for 47 hours) versus Atosiban (dosage: bolus injection of 6,75 mg i.v. in 1 minute, followed by a 18 mg/hour for 3 hours followed by a maintenance dosage of 6 mg/hour for 45 hours) for 48 hours.

#### Study burden and risks

As we compare two strategies that are already applied in current practice, no additional risks or burden are expected from the study.

# Contacts

**Public** Academisch Medisch Centrum

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

## **Inclusion criteria**

Women \* 18 years old with a singleton pregnancy with a gestational age of 24-34 weeks in threatened preterm labour, as defined by:

 $\ast$  Uterine contractions, at least 3 contractions per 30 minutes and a cervical length of  $\ast$  10 mm ór

\* Uterine contractions, at least 3 contractions per 30 minutes and a cervical length of 11-30 mm ánd a positive Fibronectin test ór

\* Ruptured amniotic membranes

## **Exclusion criteria**

- Vaginal bleeding
- Cerclage
- Cervical dilatation > 30 mm
- Previous treatment for preterm contractions
- Hypertension / anti-hypertensive agent
- Myocardial infarction (<1 month)
- Unstable angina pectoris

# Study design

## Design

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

## Recruitment

NL

4 - Nifedipine versus Atosiban in the treatment of threatened preterm labour: APOST ... 23-06-2025

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2011
Enrollment:	500
Туре:	Actual

# Medical products/devices used

Product type:	Medicine
Brand name:	Adalat
Generic name:	Nifedipine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Tractocile
Generic name:	Atosiban
Registration:	Yes - NL intended use

# **Ethics review**

Approved WMO	
Date:	23-11-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-11-2012
Application type:	Amendment
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	EUCTR2009-015782-30-NL
ССМО	NL29324.018.09