# Atosiban versus placebo in the treatment of late threatened preterm birth (APOSTEL VIII).

Published: 21-06-2017
Last updated: 15-05-2024

The aim of this study is to investigate if tocolysis with atosiban in late preterm birth (30 to 34 weeks) is (cost-) effective compared with placebo in improving neonatal morbidity and mortality.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Pregnancy, labour, delivery and postpartum conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54673

**Source**
ToetsingOnline

**Brief title**
APOSTEL VIII

### Condition

- Pregnancy, labour, delivery and postpartum conditions

**Synonym**
theatened preterm labour, threatened preterm birth

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** atosiban, threatened preterm birth, threatened preterm labour, tocolysis

## Outcome measures

### Primary outcome

The primary outcome is a combined perinatal outcome of severe neonatal morbidity and perinatal mortality.

### Secondary outcome

Secondary outcome measures include birth <48 hours, time to delivery, gestational age at birth, admission to the Neonatal Intensive Care Unit (NICU), total number of days alive outside the hospital counted from 37 weeks gestation until corrected age of three months, maternal morbidity, adverse effects and cost.

# Study description

### Background summary

Theatened preterm birth complicates 20,000 pregnancies annually in the Netherlands. Tocolysis is historically a part of the treatment, but the effectiveness of the treatment has never been proven. The WHO has recently stated that the use of tocolytica should be reconsidered.

### Study objective

The aim of this study is to investigate if tocolysis with atosiban in late preterm birth (30 to 34 weeks) is (cost-) effective compared with placebo in improving neonatal morbidity and mortality.

### Study design

Multicenter randomized placebo-controlled clinical trial with a cost-effectiveness analysis.

**Intervention**

Tocolysis with atosiban versus placebo.

**Study burden and risks**

The burden is very low as well as the risks involved.

# Contacts

**Public**
Academisch Medisch Centrum

Meibergdraaf 9
Amsterdam 1105 AZ
NL
**Scientific**
Academisch Medisch Centrum

Meibergdraaf 9
Amsterdam 1105 AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

## Inclusion criteria

Women >= 18 years old with a singleton or twin pregnancy with a gestational age between 30 0/7 and 33 6/7 weeks with threatened preterm birth defined by regular uterine contractions, and one of the following:
- Cervical length of <= 15 mm or
- Cervical length of 15-30 mm and a positive fFn test or in case of absence of cervical length measurement in local protocol a positive Fibronectin test or

Partus test
- Ruptured amniotic membranes

### Exclusion criteria

- Previous treatment for threatened preterm birth with corticosteroids in current pregnancy.
- Contra indication for tocolysis
- Signs of fetal distress
- Signs of intra uterine infection
- Fetal chromosomal or severe congenital abnormalities

## Study design

### Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 04-12-2017 |
| Enrollment: | 745 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Tractocile |
| Generic name: | atosiban |

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| Registration: | Yes - NL intended use |

## Ethics review

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| Approved WMO Date: | 21-06-2017 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 06-07-2017 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-08-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 16-10-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 01-11-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 12-04-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 26-04-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

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| Approved WMO Date: | 23-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 17-01-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 11-03-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-03-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-04-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 04-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 19-11-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-11-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |

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| Date: | 28-07-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 29-07-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 12-11-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-07-2022 |
| 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

ID: 25764
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2017-001007-72-NL |
| CCMO | NL61439.018.17 |
| OMON | NL-OMON25764 |