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

Published: 21-06-2017
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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.

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

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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

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

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

Medical products/devices used

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

Registration:	Yes - NL intended use

Ethics review

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

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	

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