Assessing the safety and effectiveness of tocolysis for preterm labour.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25764

Source
Nationaal Trial Register

Brief title
APOSTEL VIII

Health condition

Threatened preterm birth
Dreigende vroeggeboorte

Sponsors and support

Primary sponsor: Academic Medical Center
P.O. box 22660
1100 DD Amsterdam
Tel. 020 - 566 9111
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome of the study will be a composite adverse perinatal outcome, consisting

of bronchopulmonary dysplasia at 36 weeks postmenstrual age (PMA), periventricular leucomalacia > grade 1, intraventricular hemorrhage > grade 2, necrotizing enterocolitis ¡Ý stage 2, retinopathy of prematurity > grade 2 or need for laser therapy, culture proven sepsis and perinatal death.

Secondary outcome

Birth within 48 hours, time to delivery, gestational age at delivery, birth weight, number of days on invasive mechanical ventilation, length of admission in NICU, asphyxia, meningitis, pneumothorax and mortality until 3 months corrected age, maternal infection, maternal side effects and costs.

Study description

Background summary

The Netherlands

Belgium

United Kingdom

Ireland

Study objective

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

Study design

Up until 3 months corrected age.

Intervention

Atosiban

Contacts

Public

-
- -

-
Scientific
-
- -

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Eligibility criteria

Inclusion criteria

- Woman ≥ 18 years old
- Singleton or twin pregnancy
- Gestational age between 30 0/7 and 33 6/7 weeks
- 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 (≥ 50 ng/mL) 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 type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-10-2017
Enrollment:	1514
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54673
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6469
NTR-old	NTR6646

Register	ID
CCMO	NL61439.018.17
OMON	NL-OMON54673

Study results