# Assessment of Perinatal Outcome by uSe of Tocolysis in Early Labour (APOSTEL IV); Nifedipine versus placebo in the treatment of preterm premature rupture of membranes

Published: 16-12-2011 Last updated: 27-04-2024

To assess whether in women with early PPROM tocolytics improve perinatal outcome.

Ethical review Approved WMO

**Status** Recruitment stopped

**Health condition type** Pregnancy, labour, delivery and postpartum conditions

Study type Interventional

## **Summary**

#### ID

NL-OMON35899

#### **Source**

**ToetsingOnline** 

#### **Brief title**

**APOSTEL IV** 

#### **Condition**

• Pregnancy, labour, delivery and postpartum conditions

#### Synonym

premature preterm rupture of membranes

## Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Academisch Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

**Keyword:** pregnancy outcome, preterm premature rupture of the outer membranes, randomized trial, tocolysis

#### **Outcome measures**

#### **Primary outcome**

The main outcome measure will be a composite neonatal morbidity status, including perinatal death, chronic lung disease, severe intraventricular haemorrhage grade 3 and 4, periventricular leucomalacia more than grade 1, proven sepsis and necrotising enterocolitis.

#### **Secondary outcome**

Secondary outcome will be birth weight, gestational age at delivery, number of days on additional oxygen, days on supported ventilation, number of days in intensive care and total days in hospital until 3 months corrected age.

# **Study description**

#### **Background summary**

In the Netherlands, preterm birth is responsible for over 80% of all neonatal deaths and 50% of childhood neurological morbidities. 25 to 40% of the cases of preterm birth start with premature preterm rupture of membranes (PPROM). This makes PPROM, in combination with preterm labor (contractions before 37 weeks' gestation) the leading identifiable cause for preterm delivery. PPROM itself complicates in approximately 3 to 5% of all pregnancies. At present, in women with PPROM tocolysis is sometimes applied, but there is no uniform guideline. It is not clear if tocolytic treatment is effective in patients with PPROM and, if so, whether the effects justify the additional costs of this treatment.

### **Study objective**

To assess whether in women with early PPROM tocolytics improve perinatal

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outcome.

#### Study design

Randomized double-blind placebo-controlled trial performed in all ten perinatal centers in The Netherlands.

#### Intervention

Random allocation to nifedipine (intervention) or placebo (control) during the period until the start of signs of active labour (\* 3 contractions per 10 minutes).

#### Study burden and risks

Participation in the study will not lay an extra burden on the patients. This treatment is used in practice these days, but the effectivity is uncertain. There is a small risk of hypotension as a result of the medication. A possible benefit for the patient is that if tocolysis proves to be effective, perinatal outcome for patients on active study medication will be better.

## **Contacts**

#### **Public**

Academisch Medisch Centrum

Meibergdreef 9 1105 AZ NL

#### Scientific

Academisch Medisch Centrum

Meibergdreef 9 1105 AZ NL

# **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

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

#### Inclusion criteria

All women with a gestational age between 24+0/7 and 33+6/7 weeks with ruptured membranes without other signs of active labour are eligible for the trial.

#### **Exclusion criteria**

Women with \*3 contractions per 10 minutes, woman with symptoms justifying start of tocolysis, women with ruptured membranes longer than 72 hour, women having signs of chorioamnionitis or signs of intra uterine infection, women whose child has signs of fetal distress (abnormal CTG, abnormal biophysical profile) or women with any contraindication for the use of nifedipine or having a maternal disease (hypertension, HELLP syndrome, preeclampsia or other) as reason for delivery.

# 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: Recruitment stopped

Start date (anticipated): 23-10-2012

Enrollment: 120

Type: Actual

## Medical products/devices used

Product type: Medicine
Brand name: Nifedipine

Generic name: Nifedipine

Registration: Yes - NL outside intended use

## **Ethics review**

Approved WMO

Date: 16-12-2011

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 07-02-2012

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 30-05-2012

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 13-07-2012

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 20-07-2012

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 21-11-2012

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 06-08-2013
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 EUCTR2011-000174-66-NL

CCMO NL35416.018.11

# **Study results**

Date completed: 18-12-2014

Actual enrolment: 46

#### **Summary results**

Trial is onging in other countries