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
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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

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

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

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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