Assessment of Perinatal Outcome by uSe of Tocolysis in Early Labour: Nifedipine versus placebo in the treatment of preterm premature rupture of membranes.

No registrations found.

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

Summary

ID

NL-OMON27174

Source
NTR

Brief title
APOSTEL IV

Health condition

Premature Preterm Rupture Of Membranes, Nifedipine, Tocolysis

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Academic Medical Center (AMC), Consortium for women's health and reproductivity studies, Obstetric research consortium

Intervention

Outcome measures

Primary outcome

1. Neonatal mortality;

2. Composite neonatal morbidity (ie. chronic lung disease, severe intraventricular hemorrhage more than grade 2, periventricular leucomalacia more than grade 1, proven sepsis, necrotising enterocolitis).

Secondary outcome

1. Gestational age at delivery;

2. Birth weight;

3. Number of days in neonatal intensive care;

4. Number of days on supported ventilation;

5. Number of days on additional oxygen;

6. Total days in hospital until 3 months corrected age;

7. Economic analysis.

Study description

Background summary

Rationale:

At present, women with premature preterm rupture of membranes (PPROM) are in some cases treated with tocolytics and in other cases not. It is unclear whether treatment with tocolytics should take place in order to delay labor.

Objective:

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

Study design:

Randomized placebo controlled trial.

Study population:

Women with PPROM between 24+0/7 and 33+6/7 weeks gestational age.

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).

Main study parameters/endpoints:

Primary outcome is composite neonatal morbidity status, i.e. severe morbidity and death at 6 months. Secondary outcomes are gestational age at delivery, number of days in neonatal intensive care and total days in hospital.

Study objective

The aim of the study is to assess whether in women with early PPROM tocolytics improve perinatal outcome.

Study design

In view of the relatively small sample size, the fact that both treatments are already applied and are both mentioned in the Dutch guidelines, an interim analysis is not planned.

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).

Contacts

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Eligibility criteria

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

1. Women with ≥3 contractions per 10 minutes;

2. Woman with symptoms justifying start of tocolysis;

3. Women with ruptured membranes longer than 72 hour;

4. Women having signs of chorioamnionitis or signs of intra uterine infection;

5. Women whose child has signs of fetal distress (abnormal CTG, abnormal biophysical profile);

6. Women with any contraindication for the use of nifedipine;

7. Having a maternal disease (hypertension, HELLP syndrome, preeclampsia or other) as reason for delivery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2012
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2012
Application type:	First submission

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
NTR-new	NL3211

Register	ID
NTR-old	NTR3363
Other	MEC AMC : 11/092
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Nijman, Tobias AJ, et al. "Nifedipine versus placebo in the treatment of preterm prelabor rupture of membranes: a randomized controlled trial: Assessment of perinatal outcome by use of tocolysis in early labor—APOSTEL IV trial." European Journal of Obstetrics & Gynecology and Reproductive Biology 205 (2016): 79-84.