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

Gepubliceerd: 20-03-2012 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27174

Bron
Nationaal Trial Register

Verkorte titel
APOSTEL IV

Aandoening

Premature Preterm Rupture Of Membranes, Nifedipine, Tocolysis

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Academic Medical Center (AMC), Consortium for women's health and reproductivity studies, Obstetric research consortium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving tijdelijk gestopt

(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3211
NTR-old	NTR3363
Ander register	MEC AMC : 11/092
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.