Nifedipine versus Atosiban in the treatment of threatened preterm labour: APOSTEL III.

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

Samenvatting

ID

NL-OMON20652

Bron
NTR

Verkorte titel
APOSTEL III

Aandoening

Tocolysis
Atosiban
Nifedipine
Preterm Labour

Tocolyse
Vroeggeboorte

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: Consortium for women's health and reproductivity studies
Obstetric research consortium
AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be a composite poor neonatal outcome, including broncho pulmonary dysplasia (BPD), periventricular leucomalacia (PVL) > grade 1, intracerebral haemorrhage > grade 2, necrotising enterocolitis (NEC) > stage 1, proven sepsis and in-hospital death.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Preterm labour is one of the most important obstetric problems throughout the Western world and occurs in approximately 10% of all deliveries. Preterm birth is the leading cause of perinatal mortality (70 %) and accounts for 40 % of severe neurological morbidity. Tocolysis for a period of two days is crucial in the treatment of threatened preterm labour, in order to allow for corticosteroids to exert their optimal effect on fetal lung development. The optimal tocolytic drug however, is subject to controversy. We hypothesize that Nifedipine as compared to Atosiban will result in an improved neonatal outcome.

Objective:

To compare the effectiveness of the tocolytic agents Nifedipine (a calcium channel blocking agent) versus Atosiban (an oxytocin receptor antagonist) in the improvement of neonatal outcome in women with threatened preterm labour (25-34 weeks gestation).

Study design:

Multicenter randomized controlled trial.

Study population:

500 pregnant women with threatened preterm labour between 25 and 34 weeks gestational age.

Intervention:

Nifedipine (dosage: 4 dd 20 mg orally for 48 hours) versus Atosiban (dosage: bolus injection of 6,75 mg i.v. in 1 minute, followed by 18 mg/hour for 3 hours followed by a maintenance dosage of 6 mg/hour for 45 hours) for 48 hours.

Main study parameters/endpoints:

The primary outcome measure will be a composite poor neonatal outcome, including broncho pulmonary dysplasia (BPD), periventricular leucomalacia (PVL) > grade 1, intracerebral haemorrhage > grade 2, necrotising enterocolitis (NEC) > stage 1, proven sepsis and in-hospital death.

Secondary outcomes will be time to delivery, gestational age at delivery, number of days on ventilation support, in NICU and total days of the baby alive outside the hospital counted from a gestational age of 37 weeks and maternal side effects.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

As we compare two strategies that are already applied in current practice, no additional risks or burden are expected from the study.

Doel van het onderzoek

The aim of the study is to compare the effectiveness of tocolysis with Nifedipine or Atosiban in pregnant women with threatened preterm labour with a gestational age between 25 – 34 weeks. We will look at neonatal mortality and morbidity, duration of pregnancy and to maternal side effects.

Onderzoeksopzet

The outcomes will be registered at time of discharge home or at 36 weeks of corrected GA in case of BPD.

Onderzoeksproduct en/of interventie

1. In the Nifedipine group, the initial dose will be 20 mg orally in the first hour, followed by 20 mg per 6 hours for the next 47 hours;

2. In the Atosiban group, a Bolus injection of 6,75 mg i.v. in 1 minute, followed by a 18 mg/hour for 3 hours followed by a maintenance dosage of 6 mg/hour for 45 hours.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women ≥ 18 years old with a singleton pregnancy with a gestational age of 25-34 weeks in threatened preterm labour, as defined by:

Uterine contractions, at least 3 contractions per 30 minutes, and one of the following:

1. Cervical length of ≤ 10 mm ór;

2. Cervical length of 11-30 mm ánd a positive Fibronectin test ór;

3. Ruptured amniotic membranes.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Vaginal bleeding;

2. Cerclage;

3. Cervical dilatation > 30 mm;

4. Previous treatment for preterm contractions;

5. Hypertension / anti-hypertensiva;

6. Myocard infarction (<1 month);

7. Unstable angina pectoris.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	21-06-2011
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-06-2011
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	NL2806
NTR-old	NTR2947
Ander register	METC AMC : 09/258
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A