Assessment of Perinatal Outcome after Sustained Tocolysis in Early Labour (APOSTEL II)

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To evaluate the effectiveness of tocolytic maintenance therapy for postponing delivery after initial 48-hour tocolytic therapy in women with threatened preterm birth from 24-32 weeks gestational age.

Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON30860

Source
ToetsingOnline

Brief title
APOSTEL II

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
threatened preterm labour

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: pregnancy outcome, preterm birth, randomized trial, tocolysis

Outcome measures

Primary outcome

The main outcome measure will be a composite neonatal morbidity status, including perinatal death, chronic lung disease (CLD) and severe respiratory distress syndrome (IRDS), intra ventricular hemorrhage (IVH) grade 3 and 4, periventricular leukomalacia (PVL) and necrotizing enterocolitis (NEC) at the calculated term date.

Secondary outcome

Secondary outcomes will be gestational age at delivery, number of days in NICU, and total days in hospital and costs.

Study description

Background summary

In the Netherlands, preterm birth is responsible for over 80% of all neonatal deaths and 50% of childhood neurological morbidity. Approximately 1800 children are born after a pregnancy of 24-32 weeks; about 75% of them as a result of spontaneous labour. Women with threatened preterm labour between 24 and 32 weeks are treated with tocolytics and steroids for 48 hours. After this period of time, 75% of these women remain undelivered, but they remain at risk for going into labour prematurely. At present, it is not clear if prolonged tocolytic treatment is effective in postponing delivery and, if so, whether the effects justify the additional costs of this treatment.

Study objective

To evaluate the effectiveness of tocolytic maintenance therapy for postponing delivery after initial 48-hour tocolytic therapy in women with threatened preterm birth from 24-32 weeks gestational age.

Study design

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

Intervention

Prior to randomization, all patients will undergo measurement of cervical length and, in case of unruptured membranes, measurement of cervical fibronectin and vaginal examination. All women will then be randomly allocated to receive either the calcium antagonist nifedipine (intervention group) or placebo (control group) for a period of 12 days.

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

Women with a gestational age between 24+0 and 31+6 weeks who are spontaneously in labour, and who have been treated for 48 hours with tocolytics.

Exclusion criteria

Women with signs of intra-uterine infection, women whose child has signs of fetal distress (abnormal CTG or biophysical profile) or major congenital malformation and women with any contraindication for the use of nifedipine or having a maternal disease (severe hypertension, HELLP syndrome, preeclampsia or other) or other 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:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	400

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	nifedipine
Generic name:	nifedipine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO
Application type:	First submission
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	EUCTR2007-003900-36-NL
CCMO	NL18675.018.07