Pessaries in mulitple pregnancy as a prevention of preterm birth

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To investigate the hypothesis that in women with a multiple pregnancy prophylactic use of a pessary will be effective in the prevention of preterm delivery and the neonatal mortality and morbidity resulting from preterm delivery. To assess in women...

Ethical review	-
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON33360

Source
ToetsingOnline

Brief title
ProTwin

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
multiple pregnancy, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical pessary, multiple pregnancy, preterm birth, prevention, prophylactic

Outcome measures

Primary outcome

The main outcome parameter is the composite morbidity rate of children in the two groups. This composite morbidity rate contains the following variables: severe Respiratory Distress Syndrome (RDS), Broncho Pulmonal Dysplasia (BPD), Intraventricular Haemorrhage II B or worse, Necrotizing Enterocolitis (NEC), proven sepsis and death before discharge from the nursery (6). They will be measured until 6 weeks after the date of delivery.

Secondary outcome

Secondary outcome measures are time to delivery, preterm birth rate before 32 and 37 weeks, days of admission in neonatal intensive care unit, maternal morbidity, maternal admission days for preterm labour and costs. At present, a longer follow-up is not planned.

Study description

Background summary

Preterm birth is the major cause of handicaps in genetically normal children despite the enormous advanced neonatal care during the last decades. So, prevention of preterm birth is the major goal of obstetrical care. However, strategies to prevent preterm birth have been largely unsuccessful.

Twin pregnancies are at high risk for preterm birth. In the Netherlands about 15% of the women with a multiple pregnancy deliver before 34 weeks of gestation. At present, about 1 in 60 pregnancies is a twin pregnancy, and about 30% of the preterm born children admitted in a neonatal care (NICU) are from twin pregnancies (Source: LVR (Dutch Obstetrical Database), LNR (Dutch Neonatal

Database)). Due to an increase in age of pregnant women and an increase in assisted reproductive technologies the incidence of twin pregnancies is still rising.

The financial burden of preterm born babies is enormous: about ¤ 1500,- per day when admitted in a NICU with the concomitant costs in case the child appears to be handicapped, for both parents as the society in general. The composite poor neonatal outcome contains severe RDS, broncho pulmonal dysplasia (BPD), intraventricular haemorrhage II B or worse (IVH), periventricular leucomalacia (PVL), necrotizing entercolitis (NEC), sepsis and death before discharge (Guinn). The prevalence of this composite neonatal outcome is 77%, 35% and 12% in children born after early preterm delivery between 24-27, 28-32 and 32-34 weeks, respectively. After 34 weeks this incidence sharply declines to less than 2% at term. The probability that a woman delivers at these gestational ages is 1.8%, 5.4% and 7.2%, respectively. In total, this means that about 8% of the multiple pregnancies will result in the death of at least one child, whereas in 7% of the pregnancies at least one of the children will remain severely disabled. Moreover, another 20% of the pregnancies results in a moderate handicap of at least one of the children.

Women with a twin pregnancy are seen by a gynaecologist for their antenatal care. Although preterm birth is known to be the most important complication of a twin pregnancy no general accepted strategy is available to prevent this condition.

Recently, it has been shown that prophylactic progesterone administration to women with a singleton pregnancy at high risk for a preterm birth significantly reduced the incidence of preterm birth. Since then, several trials have been set up to assess whether progesterone is effective in the prevention of preterm birth in women with a multiple pregnancy. The first trial that was published on this subject disappointingly showed no effect of progesterone in the prevention of preterm birth in these women.

At present, this issue is also investigated in our nationwide consortium for obstetric trials. Our trial has at present recruited 560 of the needed 660 women, and is supposed to be completed in July 2009. Several other trials will be completed also.

Although a no data are known at present, we anticipate a negative treatment effect.

In this proposal, we aim to evaluate an intervention with a cervical pessary that will be inserted any time between 12 and 20 weeks and continued till delivery or 36 weeks gestation, whatever comes first.

With this design the hypothesis whether the use of a cervical pessary can reduce the preterm birth rate in twin pregnancies and its concomitant composite

neonatal morbidity can be answered.

Study objective

To investigate the hypothesis that in women with a multiple pregnancy prophylactic use of a pessary will be effective in the prevention of preterm delivery and the neonatal mortality and morbidity resulting from preterm delivery.

To assess in women with a multiple pregnancy the cost-effectiveness of a pessary in the prevention of preterm delivery and the neonatal mortality and morbidity resulting from preterm delivery.

Study design

Multicenter randomised study. The study will not be blinded. The study will be stratified for parity (previous vaginal delivery or not), chorionicity (multichorial versus monochorial) and number of multiples (twin or higher order gestation).

Intervention

Eligible women will be randomly allocated to receive either a cervical pessary or no intervention. The cervical pessary will be placed in situ at 16 to 20 weeks, and will stay in situ up to 36 weeks gestation.

Study burden and risks

De burden and risks for women participating in this study will be minimal. When a patient is randomly selected to use a pessary, it wil be placed between 16 and 20 weeks gestation. The number of visits to the outpatient clinic will not differ much from the number of normal visits during a multiple pregnancy. The women will undergo an ulstrasound measurement of the cervix, which in some participating centres is standard protocol for women with a multiple pregnancy.

Next to this research intervention cases are treated according to the local protocol in the participating clinics and other interventions i.e. tocolysis and corticosteroids in case of a threatened preterm birth.

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 presenting with a multiple pregnancy (monochorionic and bichorionic) between 12 and 20 weeks of gestation are eligible for the study

Exclusion criteria

Women with multiple pregnancies in which at least one of the fetus(es) has major congenital anomalies known at study entry will not be included

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	660
Type:	Actual

Medical products/devices used

Generic name:	cervical pessary
Registration:	Yes - CE intended use

Ethics review

Not available

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
CCMO	NL26941.018.09