Long term outcomes following a pessary placement to pregnant woman with a multiple pregnancy: 3 year follow-up of the ProTwin trial

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Now that the ProTwin study has shown an important benefit of pessary use in woman with a short cervix in twin pregnancy, long term follow-up is needed to show that there is no potential harm in using a pessary for preterm delivery prevention. We...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40439

Source
ToetsingOnline

Brief title
ProTwinkids

Condition

- Other condition
- Neonatal and perinatal conditions
- Cognitive and attention disorders and disturbances

Synonym
Mental and Psychomotor development

Health condition

motorische ontwikkeling

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Follow-up, Pessary, Preterm birth, Twins

Outcome measures

Primary outcome

The mean scores on the Bayley (mental and motor) scales. The mean scores of the Bayley in the general population is 100. A mean score below 92,5 (0,5 Standard Deviation, SD) is defined as clinically relevant. A sample size of 86 in each group (n=172) will have 90% power to detect a difference in means of 7,5 (the difference between a Group 1 mean of 100 and a Group 2 mean of 92,5 assuming that the common standard deviation is 15 using a two group t-test with a 0,05 two-sided significance level ß of 0.20. This means that a total of 69% should be reached in the follow-up and only 31% can be missed due to loss to follow-up or other reasons.

Secondary outcome

The scores in the ASQ, CBCL, general health status and maternal fertility questionnaires will be evaluated in secundary analyses.
Comparison of the pessary group with the no-pessary group will be performed.
For the ASQ questionnaire an abnormal score is a score of *2SD below the expected mean of a reference population. For the CBCL questionnaire for each scale, a strandardized T-score will be calculated. An abnormal T-score is a

score at the >97 percentile. Scores on the general assessment questionnaire will be used for correction if there are relevant differences on the baseline characteristics.

Univariate regression analysis will be performed to test the predictive value of a multiple antepartum variables on the neurodevelopmental and health related outcomes.

Mortality

Besides developmental outcomes we will register all children who died between the short term and long term follow-up. The possible difference in percentage will be tested for significance using Chi-square test.

Study description

Background summary

Preterm birth is a major cause of handicaps in genetically normal children despite the enormous advance in neonatal care during the last decades. Therefore prevention of preterm birth is the major goal of obstetrical care. However, strategies to prevent preterm birth have been largely unsuccessful. It has been suggested that the use of a cervical pessary reduces the risk of preterm delivery (1;2).

Twin pregnancies are at high risk for preterm birth. In the Netherlands about 50% of the women with a multiple pregnancy deliver before 37 weeks of gestation and 15% before 34 weeks of gestation (3). 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 (4;5). 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 ProTwin study was a Multicenter randomized study investigating the hypothesis that prophylactic use of a cervical pessary will be effective in the prevention of preterm delivery and the neonatal mortality and morbidity

resulting from preterm delivery in multiple pregnancy. In conclusion, the study shows that in women with a multiple pregnancy prophylactic use of a cervical pessary does not reduce poor perinatal outcome. However, in women with a relative short cervix at 16-22 weeks, a pessary significantly reduces both poor perinatal outcome and very preterm birth rates

Study objective

Now that the ProTwin study has shown an important benefit of pessary use in woman with a short cervix in twin pregnancy, long term follow-up is needed to show that there is no potential harm in using a pessary for preterm delivery prevention.
We expect that the ProTwin study is going to have an extended global impact. To our knowledge there is no long term information on the use of pessary during pregnancy. Therefore there is a need for long term follow up information.

Study design

A developmental questionnaire called Ages and Stages Questionnaire (ASQ), a behavioral questionnaire called Child Behavior Checklist (CBCL) and a general questionnaire concerning the general health status will be used. These tests will be used as screening tool to see if there is a potential harm using a pessary on the long term.

A more extended follow-up of the children whose mother had a cervical length of *38mm (n= 268 children) at three years corrected age. The reason for choosing this subgroup for a more extended follow-up is because this is the group that showed a significant positive result on the use of a pessary (mainly on a different rate of prematurity).

Study burden and risks

The Bayley scales have a positive approach. The tests focus on the abilities instead of disabilities often experiences as fun by the children and parents. For the age of 3 years the test will endure approximately 90 minutes. The tests is safe with no risk of harm, and is used as a standard test in the follow-up of premature born children at the age of two in the Netherlands. Therefore there is no need for study-insurance.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All patients who were randomized in the ProTwin study (n<=1634 children). A more extended follow-up of all the children whose mother had a cervical length of *38mm will also be performed (n<=268).

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive
Masking: Single blinded (masking used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2014
Enrollment:	1634
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2014
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
CCMO	NL46768.018.13