Amnioninfusion or expected management after midtrimester PPROM * what are the long-term effects on offspring*s general health and neurobehavioral development?

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The long-term follow-up of the PPROMEXIL-III trial is designed to evaluate the effect of amnioninfusion on offspring*s neurological development, lung function and general health.

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

Summary

ID

NL-OMON45320

Source
ToetsingOnline

Brief title
Follow-up of the PPROMXIL-III trial

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Preterm premature rupture of membranes and long-term development

Health condition

Cognitieve, neuromotorische en longfunctie 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: Amnioninfusion, Cognitive- and neurological development, Long-term follow-up, Midtrimester preterm premature rupture of membranes

Outcome measures

Primary outcome

Child*s neurological development

Secondary outcome

At age 2-3 years:

- Child*s cognitive development

- Child*s languages development

- Child*s behavior and social-emotional development

- Child*s attention difficulties

- Child*s general health and psychological problems (diseases, hospital

admissions)

- Child*s growth (height, weight, head circumference)

- Child*s pulmonary function and respiratory problems

- Quality of life of women who participated in the PPROMEXIL-III trial

Study description

Background summary

Preterm premature rupture of membranes (PPROM) before or near the limit of viability is associated with high perinatal morbidity and mortality. Stillbirth after an infection, abruption or cord prolapse, prematurity and respiratory problems are the major causes of perinatal mortality and morbidity in this group of babies.

Studies have suggested that oligohydramnios is the most important predictor of perinatal mortality in very early PPROM and that adequate residual amniotic fluid plays a critical role in determining either the risk for infections, such as chorioamnionitis and neonatal infection or the prevalence of pulmonary hypoplasia. Adequate amniotic fluid volumes might be associated with better outcomes in pregnancies affected by very early PPROM. Locatelli et al found that pregnancies with a median residual amniotic fluid pocket persistently less than 2*cm were at highest risk of poor perinatal and long-term neurological outcome while pregnancies with a pocket greater than 2*cm had significantly better perinatal outcome (73*92% survival) and lower pulmonary hypoplasia rates.

Serial transabdominal amnioinfusion (AI) aiming to restore the amniotic fluid volume in pregnancies complicated by very early PPROM is an invasive procedure which has the potential to improve the perinatal outcome. However, there is no solid evidence to incorporate this seemingly safe procedure in daily practice. Therefore there is the need to assess the role of amnion infusion after midtrimester PPROM. The PPROMEXIL-III trial is designed to investigate the effect of this intervention. The hypothesis underlying the PPROMEXIL-III trial is that amnioninfusion will relieve oligohydramnios and therefore improve fetal outcome by preventing pulmonary hypoplasia and neurological complications. Furthermore, it may increase time to delivery interval, and improve fetal biophysical profile through prevention of umbilical cord compression.

Long-term outcomes for surviving infants after amnioninfusion are rarely reported and long-term effects on offspring*s general health, lung function and neurobehavioral development remains unclear. Without long-term follow-up it is impossible to determine what approach is best to manage women with midtrimester PPROM. We therefore aim to conduct a long-term follow-up of patient*s offspring. The long-term follow-up of the PPROMEXIL-III trial is designed to evaluate the effect of amnioninfusion on offspring*s cognitive- and neurobehavioral development, lung function and general health.

Study objective

The long-term follow-up of the PPROMEXIL-III trial is designed to evaluate the effect of amnioninfusion on offspring*s neurological development, lung function and general health.

Study design

Follow-up of a multicenter randomized controlled trial (approved by METC AMC, NL36645.081.11, NTR 3492). The long-term follow-up of the PPROMEXIL-III trial will study the offspring of women with midtrimester PPROM and oligohydramnios during pregnancy who have been randomized for amnioninfusion or expected management.

Data from this follow-up study will be coupled to data of the PPROMEXIL-III study. In the PPROMEXIL-III patients and their offspring have been asked to attain follow-up. In the follow-up of the PPROMEXIL-III trial no further intervention will be done. Women will be asked to fill out four questionnaires about their children (a general questionnaire, Infant Toddler Sensory Profile (ITSP), Emotional Assessment (ITSEA) and a questionnaire regarding respiratory symptoms, such as asthma or other lung problems) and a questionnaire on quility of life afther the PPROMEXIL-III study. Furthermore, a physical examination and a cognitive- and neurodevelopment assessment will be obtained from these women*s offspring.

Study burden and risks

Women who participated in the PPROMEXIL-III trial will be asked to fill out questionnaires on general health, the way their child processes sensory information, and behaviour development of their offspring. In order to investigate the long-term effects of the PPROMEXIL-III trial on offspring, children born from women who participated in the PPROMEXIL-III will be investigated in a single visit, using a neurodevelopmental assessment (Bayley-III) and a physical examination. Participation in the follow-up trial is not associated with risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Women who participated in the PPROMEXIL-III trial and their offspring (singletons born in the PPROMEXIL-III trial). The PPROMEXIL-III trial has been registrated as: NL36645.081.11, NTR 3492.

Exclusion criteria

None. This is a follow-up study, all women and their offspring who participated in the PPROMEXIL-III trial can participate.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2018
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2018
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	NL58495.018.16