Cognitive-, neurodevelopment and long-term health follow-up of children born after preterm prelabor rupture of membranes.

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The goal of this study is to assess the long-term impact on child*s cognitive- en neurodevelopment, growth and health in children born from mothers with preterm prelabor rupture of membranes (PPROM) between 34 and 37 weeks* gestation.

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

Summary

ID

NL-OMON47933

Source
ToetsingOnline

Brief title
PPROMEXIL Follow-up

Condition

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

Synonym
Preterm prelabor rupture of membranes and long-term cognitive- en neurodevelopment

Health condition

Lange termijn 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: Cognitive-, Long-term follow-up, neurodevelopment, Preterm premature rupture of membranes

Outcome measures

Primary outcome

Primary Objective: Child*s cognitive development.

Secondary outcome

Secondary outcome: Child*s motor-, academic-, and behavioural development.

Child*s general health (diseases, hospital admissions), child*s growth; as

measured by length, weight, body composition, head circumference, blood

pressure and child*s pulmonary function and respiratory problems.

Study description

Background summary

Preterm birth (PTB) is one of the largest single conditions in the Global Burden of Disease analysis given the high neonatal mortality and the considerable risk of lifelong impairment. Preterm prelabor rupture of the membranes (PPROM) complicates approximately 3 percent of pregnancies and leads to one third of preterm births. The management of PPROM has been debated for a long time. Recently several randomized controlled trials have been published on the management of late PPROM, evaluating induction of labour vs. expectant management. They concluded that in absence of any clear signs of infection or fetal compromise, a policy of expectant management with appropriate surveillance of maternal and fetal wellbeing should be followed in pregnant women who present with ruptured membranes close to term. However, a recent

study performed in our lab shows that, two years after delivery, expectant management in women with late PPROM might be associated with an increase in neurodevelopmental difficulties of their offspring at the age of two as compared to induction of labour.

Study objective

The goal of this study is to assess the long-term impact on child*s cognitive- en neurodevelopment, growth and health in children born from mothers with preterm prelabor rupture of membranes (PPROM) between 34 and 37 weeks* gestation.

Study design

Follow-up of a multicenter randomized controlled trial (PPROMEXIL trial registered as ISRCTN05689407, PPROMEXIL II approved by the Medical Ethics Committee of the Maastricht University Medical Center as an amendment of the PPROMEXIL trial: MEC 05-240). The long-term follow-up of the PPROMEXIL trials will study the offspring of women with late PPROM during pregnancy who have been randomized for induction of labour or expected management. Data from this follow-up study will be coupled to data of the PPROMEXIL and PPROMEXIL-II study.

In the follow-up of the PPROMEXIL trials women will be asked to fill out four questionnaires about their children (a general questionnaire, Short Sensory Profile questionnaire, the Child Behavior Checklist and a questionnaire regarding respiratory symptoms (ISAAC), such as asthma or other lung problems). Teachers wil be asked to fill out a questionnaire on school attianment (TRF). Furthermore, a cognitive- and a neurodevelopment assessment (resp. WISC-V, CWIT and M-ABC-2) and a physical examination (including the puberty developmental scale) will be obtained from these children.

Study burden and risks

In order to investigate the long-term effects of the PPROMEXIL trials on offspring, children born to women who participated in the PPROMEXIL and PPROMEXIL-II trials will be investigated in a single visit. Patients and their children will be asked to travel to a local hospital in their neighbourhood. Assessment of children has a playful approach, is enjoyable for most children and is not invasive. Participation in this follow-up trial is not associated with any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Singletons born to women who participated in the PPROMEXIL or PPROMEXIL-II trial (PPROMEXIL trial registered as ISRCTN05689407, PPROMEXIL-II approved by the Medical Ethics Committee of the Maastricht University Medical Center as an amendment of the PPROMEXIL trial: MEC 05-240).

Exclusion criteria

None. This is a follow-up study, all singletons included in the PPROMEXIL or PPROMEXIL-II 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):	03-08-2018
Enrollment:	719
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2019
Application type:	Amendment
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	NL58494.018.16