# Assessment of Amnioninfusion for improving perinatal outcomes after midtrimester preterm prelabour rupture of membranes (PPROMEXIL III)

Published: 02-11-2011
Last updated: 15-05-2024

This study will answer the question if (repeated) abdominal amnioninfusion after midtrimester PPROM with associated oligohydramnios improves perinatal survival and prevents pulmonary hypoplasia and other neonatal morbidities. Moreover, it will...

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| **Ethical review** | - |
| **Status** | Recruitment stopped |
| **Health condition type** | Neonatal and perinatal conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39269

**Source**
ToetsingOnline

**Brief title**
PPROMEXIL III

### Condition

- Neonatal and perinatal conditions
- Congenital respiratory tract disorders

**Synonym**
Perinatal mortality. The number of stillbirths and deaths in the first week of life

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Amnioinfusion, Midtrimester, Perinatal outcome, Preterm prelabour rupture of fetal membranes (PPROM)

## Outcome measures

### Primary outcome

Primary outcome is perinatal mortality.

### Secondary outcome

Secondary outcomes are: Lethal pulmonary hypoplasia, non-lethal pulmonary hypoplasia, survival till discharge from NICU, neonatal mortality, chronic lung disease (CLD), number of days ventilatory support, necrotizing enterocolitis (NEC) more tha stage I, periventricular leucomalacia (PVL) more than grade I, severe intraventricular hemorrhage (IVH) more than grade II, proven neonatal sepsis, gestational age at delivery, time to delivery, indication for delivery, succesfull amnioninfusion, placental abruption, cord prolaps, chorioamnionitis, fetal trauma due to puncture.

# Study description

### Background summary

Babies born after midtrimester preterm prelabour rupture of membranes (PPROM) are prone to neonatal pulmonary hypoplasia. Perinatal mortality after this complication is high. Oligohydramnios in the midtrimester following PPROM is considered to cause a delay in lung development. Repeated transabdominal amnioninfusion with the objective to alleviate oligohydramnios might prevent

this complication and might improve neonatal outcome in general.

### Study objective

This study will answer the question if (repeated) abdominal amnioninfusion after midtrimester PPROM with associated oligohydramnios improves perinatal survival and prevents pulmonary hypoplasia and other neonatal morbidities. Moreover, it will assess the risks associated with this procedure.

### Study design

Randomized controlled trial (multicentre).

### Intervention

Random allocation to (repeated) abdominal amnioninfusion (intervention) or expectant management (control).

### Study burden and risks

Women with PPROM before 24 weeks with oligohydramnion participating in the trial and being allocated to the intervention group will undergo weekly amnioninfusion in a tertiary centre. They will undergo twice weekly ultrasound assessment, and if oligohydramnion re-occurs or persists, weekly transabdominal amnion infusion. This procedure consists of infusion of a sterile solution through a large bore needle inserted through the abdominal wall under ultrasound guidance. This procedure is not different from amniocentesis except fluid is instilled rather than removed. Risks described by this procedure are premature labour and delivery, fetal loss, fetal trauma, infection, uterine perforation, placental abruption. Patients allocated to the conservative group will be managed according to the strategy applied in the current practice. Patients with midtrimester PPROM are usually hospitalized after 24 weeks in a tertiary center. All patients will undergo weekly assessment of ultrasound parameters used in prediction of pulmonary hypoplasia.

## 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 with a singleton pregnancy who were first diagnosed between 16 and 24 weeks gestational age with oligohydramnios secondary to PPROM, at least 72 hours after PPROM was diagnosed, but no longer than 21 days after the diagnosis of oligohydramnion, are eligible for the trial.

## Exclusion criteria

Women having signs of premature uterine contractions, intra uterine infection, or women having a maternal disease (hypertension, HELLP syndrome, preeclampsia or other) as reason for delivery. Placental or major structural fetal anomalies. Signs of cervical incompetence. Women whose child has signs of fetal distress (abnormal biophysical profile).

# Study design

## Design

Study type: Interventional

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

**Primary purpose:** Prevention

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-06-2012 |
| Enrollment: | 56 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 26-04-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 11-07-2014 |
| 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

ID: 26522
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL36645.018.11 |
| OMON | NL-OMON26522 |