# Assessment of Amnioninfusion for improving perinatal outcomes after midtrimester preterm prelabour rupture of membranes.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26522

**Source**
Nationaal Trial Register

**Brief title**
PPROMEXIL III trial

**Health condition**

Perinatal mortality. The number of stillbirths and deaths in the first week of life.
Perinatale sterfte. Het aantal doodgeborenen en doden in de eerste levensweek.
Keywords: Midtrimester preterm prelabour rupture of
membranes. Perinatal outcome. Oligohydramnios. Amnioinfusion.

### Sponsors and support

**Primary sponsor:** Academical Medical Centre Amsterdam
**Source(s) of monetary or material Support:** Academical Medical Centre Amsterdam

### Intervention

## Outcome measures

### Primary outcome

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

### 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 l, periventricular leucomalacia (PVL) more than grade l, severe intraventricular hemorrhage (IVH) more than grade ll, 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

Background of the study:

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.

Objective of the study:

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).

Study population:

Women with PPROM and persisting oligohydramnios between 16 and 24 weeks gestational age.

Intervention:

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

Primary study parameters/outcome of the study:

Primary outcome is perinatal mortality.

Secundary study parameters/outcomes of the study:

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 than 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 objective

It is unclear whether amnioninfusie improves the outcome after premature rupture of membranes without contractions in the second trimester of pregnancy. Premature rupture of membranes usually leads to perinatal morbidity and mortality. There are indications that amnioninfusie improves perinatal outcomes, but there is no solid evidence to support incorporation of this technique into daily practice. 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

The status of these endpoints will be evaluated at six months after the expected date of delivery.

## Intervention

After amniotic fluid loss has been objectivates and a decreased amount of amniotic ultrasound has been diagnosed, structural abnormalities have been excluded by advanced ultrasound examination (this is routine care), and other criteria are met, patients can be randomized.

Treatment in the amnioninfusion arm of the study consists of the following: The abdomen of the pregnant woman is prepared in a sterile way. With ultrasound, a pocket of amniotic fluid identified herein a needle is inserted. By aspiration of a small amount of amniotic fluid the correct position is identified. After this, the desired amount of fluid (defined by the amount of weeks of gestation times 10 ml Ringer's solution),is introduced by means of an infusion pump or manually, this at a rate of about 25-50 ml per minute. After this a brief period of observation. After two days, Ultrasound assessment of the general fetal condition (presence of child movement) is performed and the amount of amniotic fluid is measured. At one week after amnioninfusion reassessment, the amount of amniotic fluid is measured, and the general fetal condition (presence of child movement) is reassessed, infection parameters in the blood are determined. The amnioninfusion is repeated weekly if it (re)appears that the amount of amniotic fluid is reduced, until the gestational age of 28 weeks is reached.

In the group allocated to the standard treatment arm biweekly checks will be performed, in the absence of amnioninfusion.

## Contacts

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# Eligibility criteria

## Inclusion criteria

Women with a singleton pregnancy complicated by oligohydramnios secondary to PPROM at a gestational age between 16 and 24 weeks, minimum 72 hours after PPROM was diagnosed, but no longer than 21 days after this diagnosis.

## Exclusion criteria

Women having signs of premature uterine contractions, intra uterine infection, or wornen 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

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

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

# Ethics review

Positive opinion

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|---|---|
| Date: | 19-06-2012 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 39269
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3331 |
| NTR-old | NTR3492 |
| CCMO | NL36645.018.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON39269 |

# Study results

**Summary results**
N/A