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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26522

Bron
Nationaal Trial Register

Verkorte titel
PPROMEXIL III trial

Aandoening

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.

Ondersteuning

Primaire sponsor: Academical Medical Centre Amsterdam
Overige ondersteuning: Academical Medical Centre Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-06-2012
Aantal proefpersonen:	56
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39269
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A