A multicentre randomised controlled trial of low versus high threshold treatment in preterm infants with progressive posthaemorrhagic ventricular dilatation.

Gepubliceerd: 29-08-2005 Laatst bijgewerkt: 13-12-2022

We hypothesize that in preterm infants with a gestational age below 34 weeks a low threshold intervention (progressive PHVD with a ventricular enlargement above the 97th centile for gestational age according to Levene and a diagonal width…

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

Samenvatting

ID

NL-OMON20414

Bron
NTR

Verkorte titel
PHVD study

Aandoening

1. Prematurity;
2. Intraventricular haemorrhage grade III (> 50 % of the ventricle);
3. Progressive posthaemorrhagic ventricular enlargement above the 97th centile for gestational age according to Levene and a diagonal width enlargement of the frontal horn above 6 mm according to Davies.

Ondersteuning

Primaire sponsor: Neonatology Intensive Care department
Erasmus MC- Sophia Children’s Hospital
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Need of ventriculoperitoneal shunt.

Toelichting onderzoek

Achtergrond van het onderzoek

Posthaemorrhagic ventricular dilatation (PHVD) is the most serious direct complication of intraventricular haemorrhage. If progressive ventricular enlargement exceeds 4 mm over the 97th centile for gestational age, PHVD carries a poor prognosis with about 50 – 60 % being shunt dependent, over 60 % disabled and about 20 % not surviving the neonatal period. However, whether lower threshold treatment for PHVD decreases the need for shunting and improves long term neurodevelopmental outcome is still under debate.
In a recent retrospective study in 5 Dutch neonatal intensive care units 95 surviving infants with a gestational age equal to or below 34 wk, diagnosed as having a grade III haemorrhage according to Volpe who developed PHVD (ventricular enlargement above the 97th centile for gestational age) were included. Intervention was not deemed necessary in 22 infants, because of lack of progression of ventricular dilatation. Low threshold intervention (progressive PHVD exceeding the 97th centile) was associated with a strongly reduced risk of ventriculoperitoneal shunting (odds ratio = 0.22, 95% confidence interval: 0.08-0.62) and a lower number with a moderate or severe handicap (5/31; 16%) compared to high threshold intervention (PHVD exceeding 4 mm over the 97th centile) (11/42; 26%).
A randomised prospective intervention study is needed to prove the beneficial role of low threshold intervention on the risk of ventriculoperitoneal shunting and neurodevelopmental outcome.

Doel van het onderzoek

We hypothesize that in preterm infants with a gestational age below 34 weeks a low threshold intervention (progressive PHVD with a ventricular enlargement above the 97th centile for gestational age according to Levene and a diagonal width enlargement of the frontal horn above 6 mm according to Davies) will decrease the need for a ventriculoperitoneal shunt as compared to high threshold intervention (PHVD exceeding 4 mm over the 97th centile according to Levene and an increase in diagonal width of the frontal horn above 10 mm according to Davies) and will improve neurodevelopmental outcome at two years of age.

Onderzoeksproduct en/of interventie

Comparison: low threshold versus high threshold intervention.
Low threshold: intervention when an
increase in ventricular width according to Levene above the 97th centile towards the P97+4 but without crossing the > P97+4 and an increase
in diagonal width according to Davies above 6 mm > towards 10 mm, but not
above 10 mm.
High threshold: intervention after an increase in ventricular width according to Levene above the P97+4 and an increase in diagonal width according to Davies above 10 mm. Intervention: Lumbar punctures (LP; 10 ml/kg) on 2 days. Cranial ultrasound is repeated
daily. If on the third day a LP is still required, a subcutaneous
reservoir will be inserted. Daily 10 cc/kg will be drained in 2 taps a
day. Punctures from the reservoir will be continued over the next days
or weeks. The amount of CSF drained will be increased or decreased in
order to reach and keep the ventricular Index according to Levene < P97
and diagonal anterior horn width < 6 mm. If punctures are still necessary
exceeding 28 days after the first LP, a ventriculoperitoneal shunt is
inserted. If the bodyweight of the infant is less than 2,5 kg, the
insertion of the shunt will be postponed until the bodyweight is over 2,5
kg, if CSF drainage is still needed then.

Contactpersonen

Publiek

Erasmus Medical Center,
P.O. Box 2060
B.J. Smit
Rotterdam 3000 CB
The Netherlands
+31 (0)10 4636363

Wetenschappelijk

Erasmus Medical Center,
P.O. Box 2060
B.J. Smit
Rotterdam 3000 CB
The Netherlands
+31 (0)10 4636363

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Premature infants with a gestational age equal to or below 34 weeks;
2. With an intraventricular haemorrhage grade III according to Volpe (> 50 % of the ventricle); and
3. With a progressive posthaemorrhagic ventricular enlargement above the 97th centile for gestational age according to Levene and a diagonal width enlargement of the frontal horn above 6 mm according to Davies.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Congenital cerebral malformation;
2. Cerebral parenchymal haemorrhage;
3. Periventricular leucomalacia > grade II according to de Vries;
4. Posthaemorrhagic ventricular dilatation already present at birth;
5. Central nervous system infection;
6. Metabolic disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL373
NTR-old	NTR413
Ander register	: MEC-2005-007
ISRCTN	ISRCTN43171322

Resultaten

Samenvatting resultaten
N/A