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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20414

Source
NTR

Brief title
PHVD study

Health condition

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.

Sponsors and support

Primary sponsor: Neonatology Intensive Care department
Erasmus MC- Sophia Children’s Hospital
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Need of ventriculoperitoneal shunt.

Secondary outcome

Neurodevelopmental outcome on the Bayley Scales of Infant Development at 24 months corrected age, assessed by a ‘blinded’ developmental psychologist.
Number of (lumbar) punctures, reservoirs, reservoir dysfunctions, reservoir infections and reservoir revisions, drains, drain dysfunctions, drain infections and drain revisions.

Study description

Background summary

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.

Study objective

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2006
Enrollment:	125
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-08-2005
Application type:	First submission

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
NTR-new	NL373
NTR-old	NTR413
Other	: MEC-2005-007
ISRCTN	ISRCTN43171322

Study results

Summary results
N/A