Reference ranges of the lateral ventricles in neonates measured by cerebral ultrasound

Published: 25-07-2006
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To establish normal ranges for the lateral ventricles in neonates with a gestational age ranging from 25 to 42 weeks.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON35406

Source
ToetsingOnline

Brief title
Cerebral ventricular size in neonates

Condition

- Increased intracranial pressure and hydrocephalus
- Neonatal and perinatal conditions

Synonym
hydrocephalus, post hemorrhagic ventricular dilation (PHVD)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cerebral ultrasound, lateral cerebral ventricle size, neonate

Outcome measures

Primary outcome

- To establish new reference values that accurately reflect normal values of

lateral ventricular size (ventricular index, anterior horn width and

thalamo-occipital distance) in infants of varying gestational ages.

- Compare these curves with the available data.

- Investigate the influence of the way of delivery on ventricular size

following birth.

Secondary outcome

not applicable

Study description

Background summary

Normal values of the size of the lateral ventricles (ventricular index, anterior horn widht, thalamo-occipital distance) have been determined in preterm infants with a GA of 25 weeks up to 42 weeks. Reference values are important to diagnose post-haemorrhagic ventricular dilatation (PHVD) and evaluate the effect of treatment if initiated.

Reference values of the more mature infants (> 34 weeks) are based on small numbers. Also, we have clinical reasons to believe that these values are not always appropriate for our population. In addition, we would like to establish reference values for the lengte of the occipital horn, as no conclusions for this clinical significant variable can be drawn from the available literature.

To establish reliable reference ranges, we would like to investigate the influence of the type of delivery on ventricular size. This will be easily achievable by repeating ventricular measurements in a part of the cohort after a few days. In preterm baby*s this is part of routine care, so no extra

ultrasounds have to be made in this group.

Study objective

To establish normal ranges for the lateral ventricles in neonates with a gestational age ranging from 25 to 42 weeks.

Study design

Prospective study involving neonates at birth. Cranial ultrasound scans will be performed within the first 3 days of life in neonates admitted to our hospital. If possible, a second cranial ultrasound will be performed after 72 hours following birth. Measurements of the lateral ventricles will be performed in a coronal and sagittal plane.

Study burden and risks

Risk and burden: cranial ultrasound is safe, non-invasive and can be performed at the bedside. In this study one or two 5 minute ultrasound examinations will be performed. Therefore, the investigators feel there is no risk and minimal burden associated with participation in this study.
Benefit: none
Group relatedness: PHVD is a problem which occurs in newborns with intracranial hemorrhage. Diagnosing intracranial ventricular dilation can only be done if accurate reference values for newborns of varying gestational ages are available. Therefore, it is necessary to conduct this research in normal newborns of varying gestational ages without intracranial abnormalities.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Postnatal age at examination < 72 hours
- gestational age: all newborn infants

Exclusion criteria

- Abnormalities on cerebral ultrasound: all grades of intraventricular hemorrhage (according to classification of de Vries), periventricular leukomalacie (PVL according to classification of de Vries), cerebral infarction, hydrocephalus, hypoxic-ischemic lesions or structural anatomic problems
- Craniospinal malformation
- Chromosomal or syndromal abnormalities
- Unclear/unknown GA
- Other major birth defects
- Absence of informed parental consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2007
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO Date:	25-07-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL12801.041.06