Early neurological outcome of prenatally diagnosed ventriculomegaly at 20 weeks of gestation standardized ultrasound scan

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Primary objective: To determine whether the short-term neurological outcome of surviving children diagnosed with prenatally diagnosed ventriculomegaly is associated with the extent of VM before birth.Second objective: To determine whether the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON38456

Source
ToetsingOnline

Brief title
Early neurological outcome of prenatally diagnosed ventriculomegaly

Condition

- Neurological disorders congenital
- Structural brain disorders
- Foetal complications

Synonym
enlarged brain ventricles, Ventriculomegaly

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Neurology, Outcome, Ultrasound, Ventriculomegaly

Outcome measures

Primary outcome

Primary endpoints: The quality of GMs (in particular fidgety movements, FMs) at 13 weeks (range 11-15) after term from video recordings, using Prechtl*s method of assessing General Movements, as Normal /Abnormal (Einspieler 1997), and additionally the assessment of the Motor Optimality Score (MOS)(quantitative score on details of the early motor repertoire, ranging from 5 (lowest optimality) to 28 (highest optimality) (Bruggink 2009).

Secondary outcome

Secondary endpoint: Information about etiology and survival will be gathered using a standard clinical form. Additionally, the quality of GMs will be assessed one week after birth, at term age (+/- 2 weeks), and at 18 weeks (+/- 2 weeks) after term age using video recordings. The recordings will last 45 minutes if before term age, and 10 minutes from term age (38 weeks postmenstrual age) onwards. Again, the GMs will be assessed as normal /abnormal, and the Motor Optimality Score will be assessed. For recordings before 42 weeks postmenstrual age we will use an age-adequate Motor Optimality Score (MOS), ranging from 8 (least optimal) to 18 (most optimal) (De Vries 2008).

Study description

Background summary

Ventriculomegaly (VM) can be diagnosed from around 18-20 weeks of gestation. It is one of the most common findings on prenatal ultrasound scan (Weichert 2010). Since the introduction of the standardized ultrasound scan at 20 weeks of gestation (SEO) in the Netherlands, the incidence of prenatally diagnosed VM has increased (Robroch 2013). The screening with SEO is offered to all pregnant women in the Netherlands.
The etiology of intrauterine VM is difficult to unravel when still in utero, and thus neurodevelopmental outcome of these children is hard to predict. Some studies have reported that mild and isolated VM are associated with more favourable neurological outcome than more severe and progressive VM but others could not confirm this finding. It is important to identify which prenatal characteristics are the best indicators of outcome later in life, in order to be able to counsel this increasing group of parents adequately. Whether the etiology, extent of the VM and other characteristics such as progression of VM or associated anomalies on ultrasound are predictors for survival and later outcome is unknown, because until now studies have shown contradictive results (Beeghly 2010, Weichert 2010).
By investigating the short-term neurological outcome of the surviving children with VM it is possible to use a non-invasive method to identify children at risk for neurological impairment. This is the qualitative assessment of General Movements (GMs) from video recordings. This method has emerged as a reliable and valid predictor of neurological outcome for the individual patient, especially of motor deficits. GMs are present from fetal life onwards until 5 months after term and can reliably be assessed in early infancy. The method is not only predictive of severe abnormalities later on, but also predictive of mild motor abnormalities and cognitive delay (Bruggink 2008, Bruggink 2009, Butcher 2009, Bruggink 2010).
In our study we aim to determine short term neurological outcome of children with prenatally diagnosed VM in relation to the extent of VM, the associated anomalies and the etiology of VM.

Study objective

Primary objective: To determine whether the short-term neurological outcome of surviving children diagnosed with prenatally diagnosed ventriculomegaly is associated with the extent of VM before birth.
Second objective: To determine whether the etiology of VM and presence of associated anomalies is associated with short term neurological outcome of children with prenatally diagnosed VM.

Study design

Prospective observational longitudinal cohort study.

Study burden and risks

Information gathering concerning etiology and outcome of the pregnancy is part of standard care for pregnant women referred to the UMCG after SEO screening (waiver Prenatal Diagnostics). The qualitative assessment of GMs from video recordings is a sensitive, non-invasive, easy to apply method to assess brain function, with good predictive value for neurological outcome. The non-invasive character of video recording does not interfere with routine clinical care since the camera will be placed in front of or next to the incubator or cot in a way that caregivers are not hindered by the camera or lose sight on monitors. Data from this study can not be obtained in another population, as we are interested in early neonatal morbidity in this specific group of children. GMs are age-sepcific and are only present from early fetal life onwards until the end of the first half year of life.
The results of this study can help for a better understanding of the mechanisms leading to neonatal morbidity and problems in neurological development in children diagnosed with ventriculomegaly in the fetal period. This is very valuable information because it will help professionals to inform and guide parents in difficult decision-making when confronted with a pregnancy complicated with fetal ventriculomegaly.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Newborn child, aged < 1 week, having been diagnosed with ventriculomegaly (>10mm ventricular width) as fetus

Exclusion criteria

Diagnosis of spina bifida

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2013
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43522.042.13