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Early outcome of prenatally diagnosed Ventriculomegaly by general movement Assessment

Submission date 19/08/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/11/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/11/2019	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 26/03/2019:
Background and study aims
Ventriculomegaly means the enlargement of the cavities (ventricles) of the brain. This can be detected in babies before they are born by ultrasound. It is unclear how it affects the baby later on in life. We know that the development of children may be abnormal and delayed if severely enlarged ventricles are found before birth. We do not know whether their development is affected by moderately enlarged ventricles. To find out about the effects, we will study the quality of general movements of babies with enlarged ventricles once they are born. This will give us an insight into how they develop.

Who can participate?
Newborn babies who were diagnosed with enlarged ventricles of the brain before birth on the ultrasound scan at 20 weeks of gestation can participate in the study.

What does the study involve?
To find out the general movements we will videotape the babies at three different time periods once they are born. This consists of filming the child when it is lying awake in its crib without interference for 10 minutes. The first filming is at the age of one week, the second at 13 weeks and the last time at 18 weeks of age. After filming we will analyse their movements as seen on videotape to assess their neurological condition between birth and 5 months to identify factors related to developmental impairments and delay.

What are the possible benefits and risks of participating?
There are no benefits for participating infants or their parents. As the filming is non-invasive, this study involves no risks for children and parents.

Where is the study run from?
The filming of the infants will take place during out-patient clinic visits or will be done at the babies homes.

When is the study starting and how long is it expected to run for?
The study started in October 2013 and will end in December 2019.

Who is funding the study?
The study is funded by the University of Groningen (Netherlands).

Who is the main contact?
Ms Janyte C. Holwerda
j.c.holwerda@umcg.nl

Previous plain English summary:
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Who is the main contact?
Ms Janyte C. Holwerda
j.c.holwerda@umcg.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Early neurological outcome of prenatally diagnosed ventriculomegaly at 20 weeks of gestation, using the qualitative assessment of general movements

Acronym
EVA

Study objectives
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 is also predictive of mild motor abnormalities and cognitive delay (Bruggink 2008, Bruggink 2009, Butcher 2009, Bruggink 2010).
In our study we aim to determine the 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical committee of the University Medical Center Groningen, the Netherlands, 24/09 /2013, ABR-number 43522.042.13

Study design
Prospective observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ventriculomegaly

Interventions
This is an observational study in which the short-term neurological outcome, etiology and survival in children with prenatally diagnosed hydrocephalus will be determined prospectively. Maternal, antenatal, perinatal and neonatal clinical and demographic data will be collected as part of standard care using a case record form.

The children of the pregnant women of whom the fetuses have ventriculomegaly (>10 mm ventricular width) will be included after birth, maximum gestational age (GA) 41+6 weeks. At the time of referral to the UMCG, this being short after the ultrasound investigation at about 20 weeks of gestation, the parents will receive an information letter from the investigator, explaining the study. When the child is born, the investigator will inform them of the study once more, and obtain informed consent.

Of the participating children, short-term neurological outcome will be determined using the standardized observation (from video recordings) of the quality of general movements (GMs). As primary outcome measure, the quality of fidgety general movements (FMs) and the motor optimality score (MOS) will be determined at 3 months (11-15 weeks) after term, from video recordings. As secondary outcome measure the quality of GMs and the MOS will be assessed at 1 week after birth, and in preterm children (born before 36 weeks) also at term equivalent age (40 weeks ± 14 days post menstrual age), and in all children around 18 weeks (16-20 weeks) after term. In this way, the developmental trajectory of GM quality from birth until 5 months post term age can be assessed. To summarize, in preterm children video recordings will be performed four times, in term-born children three times.
On day seven after birth, we will use a digital video camera placed on a tripod 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 the monitor. At corrected full-term age, 13 weeks post term 18 weeks post term videotape recording will take place during a normal outpatient clinical visit or at home and will last 10 minutes. All recordings will be evaluated off-line using Prechtl´s method of assessing GMs (including quality of FMs). At least one observer will be unaware of the clinical course. In addition to and following the assessment of GM (FM) quality we assess the motor optimality score (MOS), the list of items being age-specific.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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.

The quality of fidgety general movements (FMs) and the motor optimality score (MOS) will be determined at 3 months (11-15 weeks) after term, from video recordings.

Secondary outcome measures
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.

As secondary outcome measure the quality of GMs and the MOS will be assessed at 1 week after birth, and in preterm children (born before 36 weeks) also at term equivalent age (40 weeks ± 14 days post menstrual age), and in all children around 18 weeks (16-20 weeks) after term.

Overall study start date
01/10/2013

Completion date
31/12/2019

Eligibility

Key inclusion criteria

1. Newborn child
2. Aged less than one week
3. Having been diagnosed with ventriculomegaly (>10 mm ventricular width) as foetus

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Diagnosis of spina bifida
2. First ultrasound at more than 23 weeks of gestation

Date of first enrolment
01/10/2013

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Pediatrics, Division of Neonatology, UMCG
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (Netherlands)

Sponsor details

Sector F
Junior Scientific Masterclass
Huispostcode FC40
Postbus 196
Groningen
Netherlands
9700 AD

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
University/education

Funder Name
University of Groningen (Netherlands) - Faculty of Medicine, Funding for MD/PhD, Junior Scientific Masterclass

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration