Normal values for ventricle volumes and cerebrospinal fluid (CSF) circulation

Published: 26-03-2009
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Obtain normal values of ventricle volumes and CSF circulation in healthy volunteers with MRI scanning.

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

Summary

ID

NL-OMON33663

Source
ToetsingOnline

Brief title
Normal values CSF

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
hydrocephaly; aqueduct stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Van Leersumfonds

Intervention

Keyword: CSF, flow, MRI, ventricles

Outcome measures

Primary outcome

Ventricle volumes and CSF circulation or flow

Secondary outcome

n.a.

Study description

Background summary

Several studies on hydrocephaly are ongoing. For these studies, normal values of healthy volunteers are needed. Up to now, normal values are not or are insufficiently available. This currently proposed study will obtain normal values of ventricle volumes and CSF circulation.

Study objective

Obtain normal values of ventricle volumes and CSF circulation in healthy volunteers with MRI scanning.

Study design

this is an observational study without intervention.

Study burden and risks

Participation in this study costs little time: time for inclusion, once travelling and scanning. Patients who are not allowed in the MRI scanner are excluded (e.g. with pace maker of claustrophobia). There are no known side effects of MRI scanning. It is in theory possible that a lesion in the brain is discovered during this study. This could have a positive effect: the patient who did not have symptoms yet can be treated at a very earlystage of the disease. On the other hand, a negative effect is possible: a untreatable lesion is discovered and the healthy volunteer will become a patient. Or else, a lesion that does not need treatment is found.
However, the scanning sequences are designed for volume measurement and flow measurement, and are not dedicated sequences for discovery of lesions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy
age 18-50 year
no contra-indications for MRI scan

Exclusion criteria

hydrocephaly / CSF circulation disorder
exclusion criteria for MRI for example pacemaker, claustrofobia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	26-03-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL25966.091.09