

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Increased intracranial pressure and hydrocephalus
<b>Study type</b>	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 or 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 early stage 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
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## 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

CCMO

### ID

NL25966.091.09