

# Visualisatie van veranderende geometrie bij halsvenen van de gezonde populatie

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	-

## Summary

### ID

NL-OMON25854

### Source

Nationaal Trial Register

### Brief title

UNEVEN

### Health condition

Chronic cerebro-spinal venous insufficiency

## Sponsors and support

**Primary sponsor:** University of Twente

**Source(s) of monetary or material Support:** University of Twente, Magnetic Detection & Imaging

## Intervention

## Outcome measures

### Primary outcome

The primary aim of this study is to evaluate the feasibility of detecting changes in size and geometry of the internal jugular and external jugular veins from supine to upright position in healthy subjects.

## Secondary outcome

The secondary aim is to evaluate the size and geometry of the veins depending on the inclination angle during scanning

## Study description

### Background summary

Background of the study:

Chronic cerebro-spinal venous insufficiency (CCSVI) is a condition characterised by anomalies in the main veins draining the central nervous system (CNS) that disturb the normal outflow of blood from the CNS to the heart. CCSVI is linked to several CNS disorders, such as idiopathic intracranial hypertension, traumatic brain injury, senile dementia and hydrocephalus. Therefore, it is important to better understand the cerebral venous pathways. Previous studies have shown that these pathways depend on the body position. In supine position, the cerebral venous drainage through the internal jugular vein (IJV) is increased compared to upright position. In upright position, the IJVs collapse and the blood goes primarily through the paravertebral venous plexus. Most of the research of cerebral venous pathways are performed in supine position, while humans spend most of the time in upright position. Studies to investigate postural changes in cerebral venous pathways may contribute to the understanding of CCSVI caused by insufficient cerebral venous drainage.

Objective of the study:

Rotating low-field MRI offers the opportunity to visualize the neck veins in different positions to study how these pathways differ with alternating body positions. For low-field MRI no standardized non-contrast-enhanced protocol is developed to evaluate the geometry of extracranial veins. This research aims to contribute to a better understanding of postural changes affecting the extracranial venous pathways. An explorative study will be conducted to evaluate the possibilities of an open 0.25T MRI-system to visualize the geometry of the IJVs and external jugular veins of healthy subjects in supine, upright and intermediate positions. The size and geometry of the veins will be measured to evaluate how these parameters relate to the postural position. This pilot study will assess the feasibility for a larger study, with the aim to identify the normal variation of geometry of the extracranial veins in different postural positions.

Study design:

This is an explorative prospective cohort study in 15 healthy volunteers. All the subjects will be volunteering students or employees of the University of Twente (UT). Each subject will be scanned in the sub-mandibular region, at scanner inclinations from 90° (sitting, analogous to upright), 69°, 45°, 21° and 0° (supine position).

Study population:

The study population consists of 15 healthy volunteers. All subjects will be recruited from the UT through pamphlets. Multiple employees and students of the UT have indicated that they would like to volunteer for MRI scans in the context of research or education. Therefore, we do not expect trouble recruiting subjects.

Primary study parameters/outcome of the study:

The primary aim of this study is to evaluate the feasibility of detecting changes in size and geometry of the internal jugular and external jugular veins from supine to upright position in healthy subjects.

Secondary study parameters/outcome of the study (if applicable):

The secondary aim is to evaluate the size and geometry of the veins depending on the inclination angle during scanning.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

The burden associated with participation is that subjects who are already daily in the TechMed Centre (University of Twente) need to visit the MRI scanner once for a scan session of 45 minutes duration. To perform the upright scan, the participant needs to sit still for 6 minutes first at 90°. After that, the MRI table will be rotated back to 69°, 45°, 21°, and 0° (=supine), where also 6-minute scans will be made. Due to the sitting position of the participants, the possible effect of experiencing dizziness or light-headedness that can occur in standing position will be much less and can be considered negligible. This is due to the possibility for the participants of using and moving the legs, which will prevent this effect from happening. Of course, participants do always have the chance to communicate with the researchers during the scan and may always indicate on their own initiative to end the investigation if they want.

## **Study objective**

Low-field MRI is the only suitable imaging modality to visualize the changing geometry in cervical veins due to its ability to image the patient in 3D both upright and supine.

## **Study design**

Both outcomes (primary and secondary) will be measured based on one time point, i.e. the MRI scan of the subject.

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

Subject is healthy and 18 years or older  
Signed informed consent

### Exclusion criteria

Length > 200 cm (because of MR table restrictions)  
Not eligible for MRI, in response to the MRI safety checklist  
History of abnormalities in or treatment of cervical veins

## Study design

### Design

Intervention model: Other  
Allocation: Non controlled trial  
**Control:** N/A , unknown

### Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-02-2021  
Enrollment: 15  
Type: Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable

Application type:

Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 50936

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL9155
CCMO	NL76280.091.20
OMON	NL-OMON50936

## Study results