Visualization of changing cervical vein geometry of the healthy population

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON50936

Source ToetsingOnline

Brief title

Upright neck vein geometry visualization with low-field MRI (UNEVEN MRI)

Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Chronic cerebro-spinal venous insufficiency and insufficient venous drainage of the brain

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente Source(s) of monetary or material Support: Ministerie van OC&W,Pioneer Award 2019

Intervention

Keyword: CCSVI, Cervical veins, Low-field MRI, Rotating MRI

Outcome measures

Primary outcome

The primairy 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 secundary aim is to evaluate the size and geometry of the veins depending

on the inclination angle during scanning.

Study description

Background summary

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 hydrocephalous. 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.

Study objective

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), $69^{\circ} 45^{\circ}$, 21° and 0° (supine position).

Study burden and risks

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, participant 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.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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

Study type:Observational non invasiveMasking:Open (masking not used)Control:Uncontrolled

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Primary purpose:

Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2021
Enrollment:	15
Туре:	Actual

Ethics review

Approved WMO	
Date:	17-02-2021
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

ID: 25854 Source: Nationaal Trial Register Title:

In other registers

Register
ССМО
OMON

ID NL76280.091.20 NL-OMON25854

Study results

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Date completed:	01-06-2021
Actual enrolment:	15

Summary results Trial is onging in other countries