Visualisatie van veranderende geometrie bij halsvenen van de gezonde populatie

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON25854

Bron
Nationaal Trial Register

Verkorte titel
UNEVEN

Aandoening

Chronic cerebro-spinal venous insufficiency

Ondersteuning

Primaire sponsor: University of Twente
Overige ondersteuning: University of Twente, Magnetic Detection & Imaging

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Chronic cerebro-spinal venous insufficiency (CCSVI) is a condition characterised by anomalies in the main veins draining the centralnervous 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 tobetter understand the cerebral venous pathways. Previous studies have shown that these pathways depend on the body position. Insupine position, the cerebral venous drainage through the internal jugular vein (IJV) is increased compared to upright position. Inupright position, the IJVs collapse and the blood goes primarily through the paravertebral venous plexus. Most of the research ofcerebral venous pathways are performed in supine position, while humans spend most of the time in upright position. Studies toinvestigate postural changes in cerebral venous pathways may contribute to the understanding of CCSVI caused by insufficientcerebral 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 withalternating body positions. For low-field MRI no standardized non-contrast-enhanced protocol is developed to evaluate thegeometry of extracranial veins. This research aims to contribute to a better understanding of postural changes affecting theextracranial venous pathways. An explorative study will be conducted to evaluate the possibilities of an open 0.25T MRI-system tovisualize the geometry of the IJVs and external jugular veins of healthy subjects in supine, upright and intermediate positions. Thesize and geometry of the veins will be measured to evaluate how these parameters relate to the postural position. This pilot studywill assess the feasibility for a larger study, with the aim to identify the normal variation of geometry of the extracranial veins indifferent postural positions.
Study design:
This is an explorative prospective cohort study in 15 healthy volunteers. All the subjects will be volunteering students or employeesof the University of Twente (UT). Each subject will be scanned in the sub-mandibular region, at scanner inclinations from 90º (sitting,analogous to upright), 69º 45º, 21º and 0º (supine position).
Study population:
The study population consists of 15 healthy volunteers. All subjects will be recruited from the UT through pamphlets. Multipleemployees and students of the UT have indicated that they would like to volunteer for MRI scans in the context of research oreducation. Therefore, we do not expect trouble recruiting subjects.
Primary study parameters/outcome of the study:
The primairy aim of this study is to evaluate the feasibility of detecting changes in size and geometry of the internal jugular andexternal jugular veins from supine to upright position in healthy subjects.
Secundary study parameters/outcome of the study (if applicable):
The secundary 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) needto visit the MRI scanner once for a scan session of 45 minutes duration. To perform the upright scan, the participant needs to sit stillfor 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 scanswill be made. Due to the sitting position of the participants, the possible effect of experiencing dizziness or light-headedness thatcan occur in standing position will be much less and can be considered negligible. This is due to the possibility for the participants ofusing and moving the legs, which will prevent this effect from happening. Of course, participant do always have the chance tocommunicate with the researchers during the scan and may always indicate on their own initiative to end the investigation if theywant.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subject is healthy and 18 years or older
Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50936
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten