Chronic Cerebrospinal Venous Insufficiency and Multiple Sclerosis: An age and sex-matched controlled Study.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON36366

Source
ToetsingOnline

Brief title
CCSVI and MS

Condition

- Demyelinating disorders
- Vascular disorders NEC

Synonym
cerebrospinal venous insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Stchting MS Research uit Voorschoten

Intervention

Keyword: CCSVI, Echo Doppler, MS, Trascranial Doppler

Outcome measures

Primary outcome

Can we find a significant difference between MS patients and healthy controles

focussed on the 5 ED parameters.

Secondary outcome

Not applicable.

Study description

Background summary

The relationship between Chronic cerebrospinal venous insufficiency (CCSVI) and multiple sclerosis (MS) is at the moment an important issue all over the world. Zamboni et al (2009) proposed a causal relationship between raised venous pressure and the inflammatory process of MS. He treated in an open-label study 65 MS patients with percutaneous transluminal angioplasty (PTA). He concluded PTA of the strictures and stenoses of the venous drainage of MS patients influence positively the clinical course and outcome compared with the preoperative assessment inclusive QOL parameters. We want to study 50 MS patients, age and sex-matched with 50 healthy controls with extracranial Echo Doppler (ED) and Transcranial Doppler (TCD). Only clinical definitive MS patients (according to the revised MCDonald criteria) will be selected. Patient demographics are age, sex, the Expanded Disability Status Score (EDSS), Multiple Sclerosis Functional Composite score (MSFC), disease course, disease duration and relapse rate Conform Zamboni et al (2009), we focus on 5 parameters indicative of CCSVI: 1-reflux in the internal jugular vein (IJV) or in the vertebral vein (VV), or both with the head in any position, 2- reflux in the deep cerebral veins, 3- high-resolution B-mode evidence of IJV stenoses, 4- flow not detected by Doppler in the IJVs or VVs, or both, and 5- reverted postural control of the main cerebral venous outflow pathways. The main point of this study is to detect in a controlled fashion if there is a relationship between CCSVI and MS.

Study objective

The main point of this study is to detect in a controlled fashion if there is a relationship between CCSVI and MS. We focus on 5 parameters indicative of CCSVI: 1-reflux in the internal jugular vein (IJV) or in the vertebral vein (VV), or both with the head in any position, 2- reflux in the deep cerebral veins, 3- high-resolution B-mode evidence of IJV stenoses, 4- flow not detected by Doppler in the IJVs or VVs, or both, and 5- reverted postural control of the main cerebral venous outflow pathways. Can we find a significant difference between MS patients and healthy controles focussed on the 5 ED parameters.

Study design

The study is an observational study. We want to study 50 MS patients, age and sex-matched with 50 healthy controls with extracranial Echo Doppler (ED) and Transcranial Doppler (TCD). Only clinical definitive MS patients (according to the revised MCDonald criteria) will be selected. Patient demographics are age, sex, the Expanded Disability Status Score (EDSS), Multiple Sclerosis Functional Composite score (MSFC), disease course, disease duration and relapse rate Conform Zamboni et al (2009), we focus on 5 parameters indicative of CCSVI: 1-reflux in the internal jugular vein (IJV) or in the vertebral vein (VV), or both with the head in any position, 2- reflux in the deep cerebral veins, 3- high-resolution B-mode evidence of IJV stenoses, 4- flow not detected by Doppler in the IJVs or VVs, or both, and 5- reverted postural control of the main cerebral venous outflow pathways.

Study burden and risks

Minimal. We do Echo Doppler; duration 60 minutes.

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

-Definite MS according the revised McDonald-criteria for MS.

Exclusion criteria

None

Study design

Design

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

Recruitment

NL
Recruitment status: Will not start

Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	27-05-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL35381.100.11