The Venous Congestion Validation Study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON46220

Source
ToetsingOnline

Brief title
VCV study

Condition

- Cardiac disorders, signs and symptoms NEC
- Vascular hypertensive disorders

Synonym
venous congestion

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Nederlandse Hartsstichting (CVON)

Intervention

Keyword: MRI, Rightheart cateterization, Venous congestion

Outcome measures

Primary outcome

Our primary endpoint will be a minimal clinically useful correlation of 0.6 or higher between right atrial pressure in mmHg measured directly during right heart catheterization, and indirectly assessed by MRI measurements of flow pattern and dimension changes of vena cava superior.

Secondary outcome

Secondary endpoints are defined as:

i. A minimal clinically useful correlation of 0.6 or higher between pressures in mmHg, measured during right heart catheterization and MRI.

ii. A minimal clinically useful correlation of 0.6 or higher between pressures in mmHg, measured during right heart catheterization and echocardiographic measurements of RAP (vena cava inferior). Additionally, echocardiographic measurement of vena jugularis interna flow will be included.

iii. The association between measurements of echocardiography and MRI.

Study description

Background summary

Rationale
Venous congestion due to elevated right atrial pressure (RAP) contributes to impaired organ function. In fact, it may be even more important than arterial hypoperfusion as it impedes drainage of blood flow, resulting in accumulation of deoxygenated blood, causing cell damage and increased fibrosis, as shown for kidney and liver function (1-3). It is, however, completely unknown if this also applies to the brain. Still, it has recently been shown that venous abnormalities are related to structural brain changes seen in cerebral small vessel disease (SVD). Jugular vein reflux measured by Duplex, which is related to RAP (4) might be related to white matter changes(5) and to increased

intracranial pressure(6). Therefore, we hypothesize that elevated RAP and venous congestion might be related to structural and functional abnormalities of the brain independently of cardiac output. By analyzing the MRI data from the Heart -Brain Connection study (multicenter CVON research), we have the unique opportunity to address this clinically highly relevant question. However, assessment of RAP and venous congestion by MRI has not yet been validated. We hypothesize that MRI measurement of flow and structure of vena cava superior is capable to estimate venous congestion with sufficient accuracy.

Study objective

Objective
The aim of this study is to validate a minimal correlation of 0.6 between right atrial pressure measure by right heart catheterization and flow and dimension of the vena cava superior determined by MRI. The correlation of >=0.6 is chosen because lower correlation would not be clinically meaningful. In addition, echocardiographic assessment of flow and dimension of the vena cava inferior will be used as comparison since this is the currently most often used tool to non-invasively assess right atrial pressure.

Study design

The study will be conducted as a content validation study in the Maastricht University Medical Centre + (MUMC+). A total of 30 patients undergoing a right-heart catheterisation for clinical purposes will be included. The indication usually is heart failure and/or pulmonary hypertension. All patients will undergo the same standardized set of clinical and imaging tests after a standardized informed consent procedure.

Study burden and risks

All research data are collected through standard medical procedures and no experimental intervention is conducted. The additional risk of this study is very low and is limited to discomfort related to the additional procedures. There will be no administration of MRI contrast media, unless clinically indicated (in case patients require an MRI due to clinical reasons, the study MRI and the clinical MRI will obviously be combined). The burden of participation consists of time investment at both baseline (60 minutes for clinical and echocardiography and a maximum of 60 minutes for MRI scanning) and the risk of fatigue. There is no direct benefit for the participants. However, this study will contribute to knowledge of hemodynamic factors associated with cognitive decline which form possible targets for future therapy.

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

* Adult patients (i.e. >18 years of age)
* Receiving right-heart catheterization for a clinical indication

Exclusion criteria

* Contra-indication for MRI or unable to undergo MRI protocol due to physical condition ;* Participation in ongoing trials for therapeutic interventions including randomized controlled trials and clinical trials of investigational medicinal products

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-12-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 22315
Source: NTR
Title:

In other registers

Register	ID
Other	NTR 7284
CCMO	NL66255.068.18
OMON	NL-OMON22315