

Venous Congestion Validation study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22315

Source

NTR

Brief title

VCV

Health condition

Heart Failure, Pulmonary hypertension, right-heart catheterization, echocardiography, MRI, hartfalen, pulmonale hypertensie, rechts kathterisatie, echocardiografie

Sponsors and support

Primary sponsor: MUMC+

Source(s) of monetary or material Support: Hartstichting (Dutch Heart Foundation)
CVON (Cardiovasculair Onderzoek Nederland)

Intervention

Outcome measures

Primary outcome

Our primary endpoint will be the differences and the correlation between pressures in mmHg measured during right heart catheterization, and MRI measurements of venous congestion parameters (flow pattern and dimension changes of vena cava superior).

Secondary outcome

- i. The differences and the correlation between pressures in mmHg, measured during right heart catheterization and echocardiographic measurements of CVP (vena cava inferior). Additionally, echocardiographic measurement of vena jugularis interna flow will be included.
- ii. The differences and the correlation between measurements of echocardiography and MRI.
- iii. Correlation between NT-proBNP and right-sided intra-cardiac pressures

Study description

Background summary

Venous congestion due to elevated central venous pressure (CVP) 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 CVP (4) might be related to white matter changes(5) and to increased intracranial pressure(6). Therefore, we hypothesize that elevated CVP 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 CVP and venous congestion by MRI has not yet been validated.

Study objective

We hypothesize that MRI measurements of flow and structure of superior vena cava is capable to estimate venous congestion with sufficient accuracy.

Study design

One visit only.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Contra-indication for MRI or unable to undergo MRI protocol due to physical condition
 - Current atrial fibrillation/atrial flutter
 - Current premature ventricular contractions (PVCs) exceeding 10% of total number of heartbeats, e.g. a heart rate of 60/min and >6 PVCs
 - BMI > 40.0 kg/m² or body habitus not suited for undergoing MRI
 - Claustrophobic patients
 - Implanted device (i.e. pacemaker, loop recorder, implantable cardiac defibrillator, neurostimulator)
 - Magnetic metals in the body that do not allow MRI
2. Participation in ongoing trials for therapeutic interventions including randomized controlled

trials and clinical trials of investigational medicinal products

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46220
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7086
NTR-old	NTR7284
CCMO	NL66255.068.18
OMON	NL-OMON46220

Study results