Venous Congestion Validation study

Gepubliceerd: 08-06-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22315

Bron
NTR

Verkorte titel
VCV

Aandoening

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

Ondersteuning

Primaire sponsor: MUMC+
Overige ondersteuning: Hartstichting (Dutch Heart Foundation)
CVON (Cardiovasculair Onderzoek Nederland)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One visit only.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult patients (i.e. >18 years of age)

2. Receiving right-heart catheterization for a clinical indication

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46220
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten