Simultaneously right heart catheterization and echocardiography in patients with pulmonary arterial hypertension to validate the non-invasive deformation-area loop

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22967

Source Nationaal Trial Register

Brief title Pressure-volume curve vs. deformation-area loop

Health condition

Patients with pulmonary arterial hypertension (PAH)

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen **Source(s) of monetary or material Support:** Radboud University Medical Center Nijmegen

Intervention

Outcome measures

Primary outcome

- The relation between the systolic slope of the deformation-area loop and the end-systolic pressure-volume relationship of the pressure volume curve.

- The relation between the slope of the diastolic part of the deformation-area loop during passive filling and the end-diastolic pressure-volume relationship of the pressure volume curve.

Secondary outcome

Other correlation between the characteristics of the deformation-area loop and the pressurevolume curve.

Study description

Background summary

Recent technical developments allow monitoring of strain and area using echocardiography. Using this information enables the production of an deformation-area loop. In this study we will investigate the relationship between the non-invasive deformation-area loop and the pressure-volume curve, during different loading conditions of the right ventricle

Study objective

Objective: The overall aim of this project is to correlate the characteristic changes of the deformation-area loop to the properties of the pressure-volume curve. We hypothesize that the systolic slope of the deformation-area loop relates to the end-systolic pressure-volume relationship of the pressure volume curve.

Study design

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Intervention

To create the pressure-volume changes we will use a balloon-catheter to partially obstruct the venous return in the Vena Cava inferior.

Contacts

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Eligibility criteria

Inclusion criteria

- strong suspicion of PAH, WHO group 1, confirmed during right hearth catheterization.
- Over 18 years of age
- voluntary

Exclusion criteria

- cardiovascular diseases, other than PAH
- diabetes mellitus

Study design

Design

Study type:

Interventional

3 - Simultaneously right heart catheterization and echocardiography in patients with ... 13-05-2025

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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Recruitment status:	Pending
Start date (anticipated):	15-01-2018
Enrollment:	20
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	10-01-2018
Application type:	First submission

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
NTR-new	NL6789
NTR-old	NTR6974
Other	CMO regio Arnhem-Nijmegen : 2017-3460

4 - Simultaneously right heart catheterization and echocardiography in patients with ... 13-05-2025

Study results