Simultaneous right heart cauterisation and echocardiography in patients with pulmonal arterial hypertension to validate the non-invasive deformation-area loop

Published: 10-10-2017
Last updated: 12-04-2024

The primary objective is to correlate the properties of the right ventricular strain-area loop to the properties of the right ventricular pressure-volume curve.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON44427

Source
ToetsingOnline

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

Condition

- Heart failures

Synonym
increased pressure in the pulmonal artery, Pulmonary arterial hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Fysiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: deformation-area loop, echocardiography, pressure-volume loop, Pulmonal arterial hypertension

Outcome measures

Primary outcome

The primary study parameters are the correlation between the different measures

for contractility and compliance from the strain-area loop and the

pressure-volume loop.

• The relation between the end-systolic pressure-volume relationship (ESPVR)

the slope of the systolic part of the strain-area loop (Sslope).

• The relation between the end-diastolic pressure-volume relationship (EDPVR)

the slope of the diastolic part of the strain-area loop during passive filling.

Secondary outcome

• dP/dT of the pressure-volume loop

• de maximale eind-systolische strain

Study description

Background summary

Pulmonary arterial hypertension (PAH) is a progressive disease, with a mean 4-year survival rate of 50 a 60%. In PAH patients a increase resistance in the pulmonary artery is present, forcing the right ventricle to produce increased pressure to circulate the same amount of blood. Due to this the right ventricle

often dilates and becomes hypertrophic which in the end results in right sided heart failure. To diagnose PAH a right (and left) heart catheterisation is used to measure the pressure in the pulmonary artery. This measurement plays an important part in the diagnosis of PAH. A big disadvantage of this technique is its invasive nature and the lack of information of the right ventricular function it provides. Due to the risks involved (due to its invasive nature) in this technique, repeated measures are not usual performed. A non-invasive alternative which provides comparable information has big advantages.
The introduction of Speckle tracking echocardiography provides the opportunity to measure ventricular wall deformation (so called strain). By combining concomitant temporal echcardiographic measures of strain (function) and volume/area (structure) of the ventricles a strain-area loop can be constructed. With this strain-area loop it is possible to measure hemodynamical changes in the heart. The strain-area loop might be able to provide comparable information as the invasive measured pressure-volume loop.

Study objective

The primary objective is to correlate the properties of the right ventricular strain-area loop to the properties of the right ventricular pressure-volume curve.

Study design

This will be an prospective, exploratory study

Study burden and risks

The included patients are already scheduled to recieve a catheterization and will be asked in advantage whether they want to participate in this study. In case of participation the patient will recieve an additional catheterization sheath through which the balloon catheter will be inserted. This sheath will be introduced using echo guidance and will have the same risks as the sheath used for the catheterization itself. During the catheterization a balloon-catheter will be inserted into the vena cava, after which this balloon will be inflated in 3 steps. The risks associated with this procedure are minor (in an pulmonary angiography, the risk at complication is 0.4%, while this procedure involves a smaller vessel and higher pressures. furthermore the most common complication is due to a contrast allergy, which is not used during the procedure in this study). The process of the balloon inflation is immediately reverseable (by deflating the balloon) in case any complication occurs during the procedure. During each phase a echocardiographic image of the heart will be produced. The additional echocardiographic images are non-invasie and not associated with any additional risks for the patient.

Contacts

Public
Selecteer

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL
Scientific
Selecteer

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Suspected pulmonary arterial hypertension
Above 18 years
Voluntary participation

Exclusion criteria

Cardiovascular diseases, other than pulmonary arterial hypertension
Diabetes Mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL61716.091.17