Prognostic value of a Non-invasive surrogate for right ventricular pressure-volume loops

No registrations found.

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

Summary

ID

NL-OMON22554

Source
Nationaal Trial Register

Brief title
Prognostic value of the deformation-area curve in PAH patients

Health condition

Pulmonal 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

1. Mortality

2. Morbidity

In case of morbidity secondary cardiovascular diseases, newly prescribed medication and surgery events will be monitored.

Secondary outcome

n.a.

Study description

Background summary

Pulmonary arterial hypertension (PAH) is a progressive disease with a mean 4-year survival rate of 50-60%. Due to an increase in pulmonary arterial resistance the right ventricle needs to adapt to the increased workload. Often this results in dilatation of the right ventricle en eventually in right sided heart failure. Nowadays right heart catheterization is used tot diagnose PAH, by measuring the pressure and volume changes over time a pressure-volume loop is created. This loop provides functional information of the right ventricle. Unfortunately right heart catheterization is an invasive procedure associated with certain risks.

A recently developed analysis technique based on echocardiographic assessments provides information about the functional information of the ventricles. This data can be used to reconstruct surrogate pressure-volume loop. Continues registration of this loop can be used to provide information of the right ventricle in a non-invasive way.

A combination of these analyzed surrogate pressure volume loops with data from patient files and municipal population register will be used in an attempt to predict mortality and morbidity in patients with pulmonary arterial hypertension.

Study objective

Objective: The overall aim of this project is to asses the prognostic value of the characteristics of an echocardiographic surrogate pressure-volume loop on mortality and morbidity due to PAH.

Study design

Echocardiographic assessments after diagnosis of PAH will be used as baseline time point to

analyze the characteristics of the surrogate pressure-volume loop. Registration of morbidity and mortality events will be used as time points to determine the prognostic value of these characteristics.

Intervention

A questionnaire regarding physical health, hospital or general practitioner visits and change in treatment will be send annually.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients diagnosed with PAH

2. NICE-group 1, NYHA classification II-IV

3. Presence of an echocardiographic assessment

4. ≥ 18 years of age;

5. Mentally able/allowed to give informed consent.

Exclusion criteria

1. Absence of an echocardiographic assessment

2. Different classification of PAH

3. Not willing to participate in this research

4. Absence of contact information

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	250
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5098
NTR-old	NTR5230
Other	CMO regio Arnhem-Nijmegen : 2015-1832

Study results