

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

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

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

Samenvatting

ID

NL-OMON22554

Bron

Nationaal Trial Register

Verkorte titel

Prognostic value of the deformation-area curve in PAH patients

Aandoening

Pulmonal arterial hypertension (PAH)

Ondersteuning

Primaire sponsor: Radboud University Medical Center Nijmegen

Overige ondersteuning: Radboud University Medical Center Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Mortality

2. Morbidity

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 and eventually in right sided heart failure. Nowadays right heart catheterization is used to 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. Continuous 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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Absence of an echocardiographic assessment
2. Different classification of PAH
3. Not willing to participate in this research
4. Absence of contact information

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
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:	01-09-2015
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5098
NTR-old	NTR5230
Ander register	CMO regio Arnhem-Nijmegen : 2015-1832

Resultaten