Pulmonary hypertension in pulmonary sarcoidosis - optimizing the diagnostic strategy

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First, non-invasive diagnostic tools can optimize the diagnostic strategy, in order to minimize the number of invasive diagnostic procedures. Second, invasive imaging of the pulmonary artery can further differentiate the mechanisms involved in...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27075

Bron
Nationaal Trial Register

Verkorte titel
PULSAR

Aandoening

Pulmonary hypertension, pulmonary sarcoidosis

Ondersteuning

Primaire sponsor: St. Antonius Hospital
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Non-invasive diagnosis of pulmonary hypertension in pulmonary sarcoidosis.

Toelichting onderzoek

Doel van het onderzoek

First, non-invasive diagnostic tools can optimize the diagnostic strategy, in order to minimize the number of invasive diagnostic procedures.

Second, invasive imaging of the pulmonary artery can further differentiate the mechanisms involved in PH associated sarcoidosis.

Onderzoeksopzet

The first timepoint is the initial diagnostic screening, including right heart catheterization and IVUS if indicated. All diagnostic procedures will be performed within weeks from each other.

The second timepoint, only for patients diagnosed as no pulmonary hypertension, is after one year of initial screening.

Onderzoeksproduct en/of interventie

All patients will be screened for the presence of pulmonary hypertension by a standardized diagnostic strategy (Local standard protocol) including history taking and physical examination, electrocardiogram and biomarkers related to pulmonary hypertension (NT-pro BNP, troponin and uric acid) and echocardiography with additional 3D-echocardiography (Ventripoint® system) in order to assess right ventricle volume and function measurements (). In a subgroup of patients with the diagnosis PH possible or likely based on the diagnostic strategy (as suggested by the international guidelines for pulmonary hypertension), right heart catheterization will be performed to measure pulmonary hemodynamics. Additionally, this will include intravascular imaging of the pulmonary artery using IVUS (Revolution® 45 MHz Rotational IVUS Imaging Catheter).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of pulmonary sarcoidosis conforming the American Thoracic Society (ATS) criteria (confirmed by histology or cytology) or by consensus of a multidisciplinary ILD-team

- Age 18 years or above

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For 3D-echocardiography:

- Pacemaker or Implantable Cardioverter Defibrillator (ICD)

For IVUS and right heart catheterization:

- Right heart mass (thrombus and/or tumor)

- Patients with coagulopathy

- Tricuspid or pulmonary valve mechanical prosthesis

- Endocarditis of tricuspid or pulmonary valve

- Frequent ventricular arrhythmias

For IVUS only

- Allergy to contrast

- Glomerular Filtration Rate (GFR) <30 mL/min/1.73m2 as calculated by the Cockcroft-Gault Equation

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-06-2015
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-07-2015

Soort:	Eerste indiening

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	NL5155
NTR-old	NTR5295
Ander register	ZonMW : 80-84200-98-15225

Resultaten