Pulmonary hypertension in pulmonary sarcoidosis - optimizing the diagnostic strategy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27075

Source
Nationaal Trial Register

Brief title
PULSAR

Health condition

Pulmonary hypertension, pulmonary sarcoidosis

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Non-invasive diagnosis of pulmonary hypertension in pulmonary sarcoidosis.

Secondary outcome

1. Assessment of the etiology of pulmonary hypertension in pulmonary sarcoidosis in patients with pulmonary hypertension.

2. Development of pulmonary hypertension after 1 year follow up for patients who are initialy diagnosed as no pulmonary hypertension.

Study description

Study objective

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.

Study design

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.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2015
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-07-2015
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	NL5155
NTR-old	NTR5295
Other	ZonMW : 80-84200-98-15225

Study results