Pulmonary hypertension in sarcoidosis: optimizing the diagnostic approach

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

Summary

ID

NL-OMON42180

Source
ToetsingOnline

Brief title
PULSAR

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
high blood pressure in pulmonary arteries, Pulmonary Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Diagnostics, Prediction, Pulmonary hypertension, Sarcoidosis

Outcome measures

Primary outcome

Main study parameter/endpoint

- Presence of PH : PH will be ruled out if there are no clinical signs of PH during screening, based on electrocardiography (ECG), biomarkers and TTE. If PH is suspected, it will be confirmed or ruled out by RHC. RHC is the gold standard for diagnosing PH.

Secondary outcome

Secondary study parameters/endpoints

- Mechanism and cause of sarcoidosis associated PH. Each case is evaluated by a multidisciplinary team consisting of a specialized pulmonologist, cardiologist and radiologist. Next to other investigations to rule out other causes of PH (sleeping study, laboratory testing etc) based on the current guidelines, the IVUS and pressure and flow wire will be used to evaluate the mechanism of disease by measuring pulsatility and local pressure/flow differences

Other study parameters

- Prediction of PH in pulmonary sarcoidosis : The third aim of this study is to find predictors for the presence of PH using non-invasive diagnostics obtained during the ILD/PH work-up.

Study description

Background summary

Sarcoidosis is a systemic inflammatory syndrome of unknown aetiology characterized by formation of non-caseating granulomas in affected tissues, particulary the lung and lymphatic system. Pulmonary hypertension (PH) is a serious complication of sarcoidosis with a suggested prevalence between 5 and 74% in patients with pulmonary involvement. PH is associated with an increased morbidity and mortality in affected patients. Different pathophysiologic mechanisms involved in PH associated sarcoidosis are: extrinsic compression of the pulmonary vessels by lymphadenopathy or fibrosis, pulmonary veno-occlusive disease, left ventricular dysfunction, portopulmonary hypertension, hypoxemia, and intrinsic sarcoid vasculopathy. The management of PH associated sarcoidosis depends on the underlying mechanism. The cornerstone in the diagnosis of PH is the right heart catheterisation (RHC). Treatment decision should be made on a case by case basis.

Study objective

The first objective of the study is to predict the prevalence of PH in sarcoidosis with pulmonary involvement, and to optimize the diagnostic approach in screening for PH associated sarcoidosis using the RHC as gold standard (Galie, 2009). The presence of disease is set by the multidisciplinary PH/ILD team using all available diagnostics (including chest CT, pulmonary function test, exercise test), but excluding the IVUS and flow measurements in the pulmonary artery.

The second objective is to predict the mechanism and cause of PH associated sarcoidosis. The mechanism of PH in pulmonary sarcoidosis is often unclear. Other investigations will be performed if *out of proportion* findings are present as discussed within the multidisciplinary PH/ILD team. The IVUS and pressure and flow wire will be used to evaluate the mechanism of disease by describing the characteristics of the vascular wall and local differences in pressure and flow. This might be helpful in patients suffering *out of proportion* PH in the presence of pulmonary sarcoidosis. This means worse hemodynamics than expected by the distribution or severity of the pulmonary fibrosis.

Study design

All patients will be screened for the presence of PH by a standardized diagnostic approach including: transthoracic echocardiography with right ventricle measurement using the Ventripoint system, electrocardiogram and biomarkers related to PH (NT * pro BNP, troponin and uric acid). In a subgroup

of patients with the diagnosis *PH possible* based on the diagnostic approach (as suggested by the international guidelines for PH), a RHC will be performed for measuring the pulmonary hemodynamics. This will also include an intra-vascular ultrasound (IVUS) and the measurements of flow in the pulmonary arteries using a specific wire.

Study burden and risks

There are no immediate benefits for participating patients. They will serve scientific research to clarify mechanisms and aetiology of PH in Sarcoidosis patients. The additional risks are kept to a minimum, since the extra invasive procedures (IVUS and ComboWire) will be executed in the same procedure as the RHC, which is not a study intervention but part of the standardized work up. Adverse events are described in the brochure of the company. They state that major risks of peripheral angiography or angioplasty (as in RHC) are:
-dissection of the blood vessel
-Abrupt closure of the blood vessel
-Perforation
-Embolization or local thrombus
-Spasm or the artery
Minor side effects are:
-bleeding at the entry puncture site
-Local or systemic infection

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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

Exclusion criteria

For 3D-echocardiography:
-Pacemaker or Implantable Carioverter 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 invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2015
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	10-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL49594.100.14
Other	nog niet bekend