The effects of treatment on the right ventricular exertional contractile reserve in chronic tromboembolic pulmonary hypertension patients

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The aim of this study is to evaluate the effects of treatment on the exertional contractile reserve and RV-arterial coupling during exercise in CTEPH patients. Furthermore, we evaluate the effects on the exertional contractile reserve and RV-...

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

Summary

ID

NL-OMON45018

Source
ToetsingOnline

Brief title
Effects of treatment on the contractile reserve in CTEPH

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
Chronic tromboembolic pulmonary hypertension, high blood pressure in the pulmonary arteries due to chronic pulmonary emboli

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic trombo embolic pulmonary hypertension, Contractile reserve, Right ventricle

Outcome measures

Primary outcome

The comparison of the rest-to-exercise response in RV contractility before- and

6 months after PEA, BPA and drug treatment.

Secondary outcome

The comparison of the rest-to-exercise response in RV-arterial coupling before-

and 6 months after PEA, BPA and drug treatment.

Study description

Background summary

Exercise tolerance and hemodynamic and right ventricular (RV) response to exercise are often abnormal in chronic thromboembolic pulmonary hypertension (CTEPH) patients after treatment, even when resting hemodynamics and resting RV function are normalized.

Study objective

The aim of this study is to evaluate the effects of treatment on the exertional contractile reserve and RV-arterial coupling during exercise in CTEPH patients. Furthermore, we evaluate the effects on the exertional contractile reserve and RV-arterial coupling during exercise within different therapies: pulmonary endartectomy (PEA), balloon pulmonary angioplasty (BPA) and drug treatment.

Study design

Observational study with minimal invasive measurements in CTEPH patients;

invasive cardiopulmonary exercise test before- and 6 months after treatment.

Study burden and risks

A right heart catheterisation (RHC) and maximal cardiopulmonary exercise test (CPET) are part of the normal clinical work-up of CTEPH patients, both pre- and 6 months post-treatment.
The burden and risks for subjects participating in this study are:
1. placement of a radial artery cannula. Placement of a radial artery cannula can be painful, therefore the radial artery cannula will be placed under local anaesthesia.
2. performing a 3 minute submaximal exercise protocol during the RHC. The risks of are the same as the known risks for RHC.
3. Increased duration time of the RHC (approximately 15 minutes).
4. Two extra blood samples at the end of the exercise protocol (2ml per sample)

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

Patients with chronic trombo-embolic pulmonary hypertension (above18 years old)

Exclusion criteria

History of left sided heart failure and/or valvular heart disease
Neuromuscular disorders preventing proper exercise testing
Arrhythmias preventing proper pressure curve recording

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):	18-10-2017
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	05-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL53924.029.15