ChanGes In Right ventricular volumes And Function Following diurEtic Treatment In Pulmonary arterial hypertension patients with decompensated right heart failure (GIRAFFE)

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The primary objective of the study is to evaluate the effect of diuretics on right ventricular function and volume properties in patients with symptomatic right heart failure and PH.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON44204

Source
ToetsingOnline

Brief title
Changes in right ventricular volumes and function

Condition

- Cardiac disorders, signs and symptoms NEC
- Pulmonary vascular disorders

Synonym
pulmonary hypertension, right heart failure

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: vici beurs

Intervention

Keyword: diuretics, pulmonary hypertension, right ventricular function, right ventricular volume

Outcome measures

Primary outcome

Change in stroke volume (SV) , Change in right ventricular ejection fraction

(RVEF) (%), Change in right ventricular end diastolic volume (RVEDV) (ml),

Change in right ventricular end systolic volume (RVESV) (ml), Change in right

atrial pressure (RAP),volume, Change in right ventricular strain.

Secondary outcome

nvt

Study description

Background summary

Patients with pulmonary arterial hypertension (PAH) and/or chronic thromboembolic pulmonary hypertension (CTEPH) with signs of congestive right heart failure are treated with loop diuretics in order to reduce fluid overload. Clinical experience shows clear symptomatic benefit of this therapy in fluid overloaded patients. However the physiological effects of diuretic treatment on the right ventricle (RV) of patients with PAH have not been studied before. Therefore, in this study we aim to investigate the physiological effects of loop diuretics on the right ventricular volumes, contractility and strain.

Study objective

The primary objective of the study is to evaluate the effect of diuretics on right ventricular function and volume properties in patients with symptomatic right heart failure and PH.

Study design

observational prospective cohort study
In order to measure RV volumes and functioncontractility (right ventricular ejection fraction, RVEF) cardiac magnetic resonance imaging (CMR) and echocardiogram will be performed before and after four weeks of treatment with an enhanced dose of loop diuretics. RV wall stress will be measured by strain measurements with CMR and by serum levels of nt-probnp NT-pro BNP.

Study burden and risks

The burden for the patient exists of one extra visit to the hospital and 1 extra MRI. There is no associated risk with participation.

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 idiopathic PAH, hereditary PAH, drug- and toxins induced PAH or chronic thrombo-embolic PH (CTEPH), according to ESC/ERS pulmonary hypertension guidelines (15)
- Symptoms of decompensated right heart failure (ankle edema, ascites, weight gain) based on the assessment and the evaluation of the pulmonologist for which an up-titration of the diuretics is indicated
- Age >=18 and <=80 years
- Able to understand and willing to sign the Informed Consent Form

Exclusion criteria

- Pregnant subjects
- Claustrophobia
- Inability to provide informed consent
- Change in PAH specific therapy during or the 3 months before the up-titration of diuretics
- Change in (dose) of any other medication.
- One or more of the following co-morbidities:, uncontrolled systemic hypertension (>140/90 mmHg) , renal failure (eGFR <30), recent diagnosis of pulmonary embolism (within 6 months).
- Contraindication for CMR imaging:
o Claustrophobia
o Implanted cardiac defibrillator or pacemaker
o Cochlear implant
o Others
- PH of any cause other than permitted in the entry criteria
- Known history of noncompliance considering therapies

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2018
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2017
Application type:	First submission
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	NL62222.029.17