# changed right heart volumes and function following diuretic withdrawal in pulmonary hypertension

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To evaluate the effect of diuretics on volumes and function of the right heart in pulmonary hypertension patients.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Cardiac disorders, signs and symptoms NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51476

**Source**
ToetsingOnline

**Brief title**
Diuretic effect on the right heart

### Condition

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

**Synonym**
pulmonary hypertension, right heart failure

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Diuretics, Pulmonary hypertension, Right heart function, Right heart volumes

## Outcome measures

### Primary outcome

Volumes: Right atrial end reservoir volume, right atrial volume at end active emptying, right atrial volume at end passive emptying, right ventricular end diastolic volume (RVEDV) (ml), right ventricular end systolic volume (RVESV) (ml)

Function: Right atrial reservoir volume, right atrial passive emptying volume, right atrial active emptying volume, right ventricular ejection fraction (RVEF) (%)

Contractility: right atrial and right ventricular strain, NT-pro BNP levels

### Secondary outcome

Other study parameters: bodyweight, 6-minute walking distance, potassium, sodium, creatinine, stroke volume, flow

# Study description

### Background summary

Patients diagnosed with pulmonary arterial hypertension (PAH) and / or chronic thrombo embolic pulmonary hypertension (CTEPH) with signs of congestive heart failure are treated with diuretics to reduce fluid overload. Clinical experience shows clear symptomatic benefits of this therapy in fluid overloaded patients. Physiological effects of diuretic treatment on the right ventricle (RV) and right atrium (RA) of patients diagnosed with PAH or CTEPH have not been studied before. Therefore, in this study we will investigate the physiological effects of diuretics on right ventricular and right atrial volumes, function and contractility.

## Study objective

To evaluate the effect of diuretics on volumes and function of the right heart in pulmonary hypertension patients.

## Study design

intervention study

## Intervention

The usual dosage diuretics as prescribed by the medical specialist will be temporarily withdrawn for one week.

## Study burden and risks

The burden of the patient exists of two extra visits to the hospital with an MRI scan, 6-minute walking distance test, venous puncture (6 ml), and body weightning. This will take a maximum of two visits of two hours. When patients have already performed measurements as routine follow-up assessment, all measurements will be performed one extra time.

Diuretic withdrawal for a one-week period can be safe in clinically stable PH patients. Diuretic withdrawal is expected to increase circulating blood volume. This can result in a right ventricular (RV) volume overload, leading to mild clinical deterioration as a consequence of RV dysfunction. Patients can experience fluid congestions as ankle edema, ascites and an increase in body weight. This mild signs are fully reversible by using diuretics as previously prescribed by their medical specialist. Risks for a cardiovascular event are negligible because solely clinically stable patients will be included without other comorbidities as systemic hypertension or renal failure. In addition, diuretics are only prescribed by a medical specialist to reduce secondary effects of right heart failure (fluid congestion). Therefore, it is expected that the hypothesized increase in preload en wall tension will solely have fluid congestion as a clinical consequence. There will be no left-sided decompensation. Therefore, fluid will not congest in the lungs and thus shall not result in shortness of breath or decreased exercise tolerance.

MRI scans are performed routinely in the VU University Medical Center. Patients have to fill in an MRI contra-indication questionnaire prior to performing an MRI. Patients with MRI contra-indications as claustrophobia or implanted cardiac device, pacemaker or cochlear implant will be excluded from this study. Patients can experience discomfort as a result of the MRI scan time of one hour.

No discomfort or risks are associated with a six-minute-walking test.
Patients can experience pain during a venous puncture. No risks are associated

with venous puncture.

## 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

- Diagnosed with idiopathic PAH, hereditary PAH, drug- and toxins induced PAH or CTEPH,
according to ESC/ERS pulmonary hypertension guidelines
- Minimal dosage of 40mg furosemide or 1mg bumetanide a day
- NYHA classification II
- Age >=18 and <=80 years
- Able to understand and willing to sign the Informed Consent Form

### Exclusion criteria

- Pregnant subjects
- Inability to provide informed consent
- Change in PAH specific therapy within 3 months before diuretic withdrawal
- Change in (dose of) any other medication
- Hospitalized for acute decompensation within one year before diuretic withdrawal
- 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
- PH of any cause other than permitted in the entry criteria
- Known history of noncompliance considering therapies

## Study design

### Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-01-2023 |
| Enrollment: | 17 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 15-11-2022 |
| 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 | NL81354.029.22 |