

# Exercise-induced pulmonary hypertension in fibrotic idiopathic interstitial pneumonias. Correlations with cardiopulmonary exercise testing

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The primary aim of this observational study is to determine the occurrence of (exercise-induced) pulmonary hypertension (sPAP > 40 mmHg) in IIP patients with an elevated V\*E/V\*CO<sub>2</sub> at AT (> 34) assessed during CPET. And, secondly to study the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39384

### Source

ToetsingOnline

### Brief title

Exercise induced PH in IIP

### Condition

- Heart failures
- Pulmonary vascular disorders

### Synonym

fibrosing interstitial lung disease, lung fibrosis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Onze Lieve Vrouwe Gasthuis

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

## Intervention

**Keyword:** Echocardiography, Exercise, IPF, Pulmonary hypertension

## Outcome measures

### Primary outcome

Main study parameters are systolic pulmonary arterial pressure and ventilatory equivalents for CO<sub>2</sub> at anaerobic threshold

### Secondary outcome

CPET parameters; peak oxygen uptake (peak V̇O<sub>2</sub>), V̇O<sub>2</sub> at the anaerobic threshold, ventilatory reserve, the ventilatory equivalent for O<sub>2</sub> and CO<sub>2</sub> (V̇E/V̇O<sub>2</sub> and V̇E/V̇CO<sub>2</sub>) at peak exercise, and oxygen-pulse (O<sub>2</sub>-pulse (V̇O<sub>2</sub>/HR)).

Baseline spirometry and diffusion capacity. Biomarkers of (left and right) ventricular strain (NT-proBNP).

## Study description

### Background summary

The development of PH at rest in patients with idiopathic interstitial pneumonias (IIP) has a negative impact on survival. Cardiopulmonary exercise test (CPET) parameters, in particular V̇E/V̇CO<sub>2</sub> at AT, may be of use to identify patients with (exercise-induced) PH. Previously, V̇E/V̇CO<sub>2</sub> at AT was shown to correlate with PH at rest; and, to be an independent predictor of mortality. In contrast, PH at rest did not predict survival in this group. It might be hypothesised that V̇E/V̇CO<sub>2</sub> at AT detects PH at exercise even before it manifests itself at rest; and, can therefore be used as a early, non-invasive prognosticator in IIP patients.

### Study objective

The primary aim of this observational study is to determine the occurrence of (exercise-induced) pulmonary hypertension (sPAP > 40 mmHg) in IIP patients with an elevated  $V^*E/V^*CO_2$  at AT (> 34) assessed during CPET. And, secondly to study the predictive value of other CPET parameters indicative of a pulmonary vascular limitation for the presence (exercise induced) pulmonary hypertension.

## Study design

Observational study

## Study burden and risks

Patients included in the study participate in investigations as part of routine clinical practice. As part of the study, an additional visit to the hospital for echocardiography during exercise is necessary. During exercise venous blood samples will be taken twice according to study protocol. The risks and physical discomforts of the investigations are to the same extend as described for exercise testing as part of routine clinical practice.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

-IIP patients, defined as IPF or fibrotic NSIP will be included in the study. Diagnosis will be made according to the ATS/ERS guidelines (1, 23).

- Informed consent

- > 18 years of age

- Male and female

### Exclusion criteria

-Occupational or environmental cause for the pulmonary fibrosis.

-Age  $\leq$  18 years of age

-Pregnancy

-Patients not able to perform a cycling test

## Study design

### Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

**Primary purpose:** Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 30-10-2013

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 30-10-2013

Application type: First submission

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	NL37917.100.12
Other	NL37917.100.12