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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	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 CO2 at anaerobic threshold

Secondary outcome

CPET parameters; peak oxygen uptake (peak V*O2), V*O2 at the anaerobic threshold, ventilatory reserve, the ventilatory equivalent for O2 and CO2 (V*E/V*O2 and V*E/V*CO2) at peak exercise, and oxygen-pulse (O2-pulse (V*O2/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 V*E/V*CO2 at AT, may be of use to identify patients with (exercise-induced) PH. Previously, V*E/V*CO2 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 V*E/V*CO2 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*CO2 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
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL

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 ill 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 <= 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