Exercise training in patients with idiopathic Pulmonary Arterial Hypertension

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1. Does exercise training improve muscle function and exercise tolerance in patients with IPAH?2. Does exercise training in IPAH result in morphological and biochemical changes of the quadriceps muscle?3. Does exercise training in IPAH result in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON30030

Source
ToetsingOnline

Brief title
Training in idiopathic pulmonary arterial hypertension

Condition

- Respiratory disorders congenital
- Pulmonary vascular disorders

Synonym
High pressure in the bloodvessels of the lungs

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting medicina interna;longziekten

Intervention

Keyword: Pulmonary arterial hypertension, pulmonary function, Quadriceps muscle, Training

Outcome measures

Primary outcome

Main study parameters:

- Change in strength and endurance of the quadriceps muscles

- Change in exercise tolerance

- Change in biochemical and morphological characteristics of the quadriceps

muscles

Secondary outcome

not applicable

Study description

Background summary

Patients with pulmonary arterial hypertension (PAH) suffer from muscle fatigue and dyspnoea. Due to right ventricular dysfunction and thereby the inability to increase cardiac output during exercise, there is decreased perfusion of the lung and reduced ability to adapt to peripheral oxygen demand. As a consequence, patients with PAH have reduced ventilatory efficiency and early muscle fatigue. Therefore, the question whether muscle dysfunction in PAH is primarily the result of disuse rather than a true myopathy needs to be answered. Biopsies of the vastus lateralis will provide information on the morphological and biochemical changes after exercise training and gives the opportunity to differentiate between deconditioning or a true myopathy.

Study objective

1. Does exercise training improve muscle function and exercise tolerance in patients with IPAH?

2. Does exercise training in IPAH result in morphological and biochemical changes of the quadriceps muscle?

3. Does exercise training in IPAH result in increased muscle mass?

4. Can IPAH patients who show a positive response to exercise training be distinguished on base of clinical parameters or specific muscle characteristics?

Study design

Study design:
In 20 patients with idiopathic pulmonary hypertension, the effect of exercise training on exercise tolerance, quadriceps function and quality of live will be assessed. Before and after a training period of 3 months, quadriceps function, exercise tolerance and quality of life will be measured. Moreover, a biopsy of the quadriceps muscles will be performed to characterize possible morphological and biochemical changes.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Blood samples and quadriceps biopsies will be taken before and after the training period at the VU medical centre. Moreover, all prior-exercise tests will take place in Amsterdam. It is tried to combine these visits with routine appointments at the hospital. Moreover, patients will be admitted to the hospital after the biopsy. To minimize the burden of travelling three times a week to the hospital, exercise training will take place at a rehabilitation centre nearby the homes of the patients.

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

- Mean pulmonary artery pressure (mPAP) > 25 mmHg
- Stable on therapy for at least 3 months
- Idiopathic pulmonary arterial hypertension

Exclusion criteria

- Presence of systemic inflammation
- Patients with pulmonary hypertension associated with collagen vascular disease, congenital heart disease, chronic thrombo-embolic pulmonary hypertension, pulmonary venous hypertension, left heart failure, hypoxemic lung disease
- Patients with musculoskeletal problems prohibiting maximal exercise performance

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Magnum Biopsy system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL11636.029.06