Exercise-induced left ventricular diastolic dysfunction in COPD patients with a symptomatic limitation to exercise

Published: 27-03-2013
Last updated: 01-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON39266

Source
ToetsingOnline

Brief title
Left ventricular diastolic function during exercise in COPD patients.

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
chronic obstructive pulmonary disease, emfysema or chronic bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W,GlaxoSmithKline,non-

restricted grant farmaceutische industrie

Intervention

Keyword: COPD, Exercise, Pulmonary hypertension, Stress-echocardiography

Outcome measures

Primary outcome

•Exercise-induced LV-DD; defined by E/E* > 15 during stress echocardiography.

Secondary outcome

•Baseline spirometry and diffusion capacity

•Inspiratory capacity, as measuer of dynamic hyperinflation

•CPET parameters: peak-V*O2,, V*E/V*CO2 and O2-pulse

•Systemic inflammation: IL-18, IL-6 and hs-CRP

•All other cardio-pulmonary exercise test parameters.

•Sub-maximal exercise (6-MWD with Borg scores).

•Daily life physical activity measured by SenseWear pro armband.

•Metabolic and muscular status (BMI and Fat-free Mass).

•Peripheral muscle strength measured by Jamar dynamometer.

•Other markers of systemic inflammation (TNF-α, and fibrinogen, IL-8, Monocyte chemoatractant protein 1 (MCP-1))

•Markers of collagen metabolism in serum (carboxyterminal propeptide of collagen 1 (PICP), aminoterminal propeptide of collagen (PINP), amino-terminal propeptide of collagen 3 (PIIINP) and carboxy-terminal telopeptide of collagen 1 (CITP)

•Matrix metalloproteinases (MMP) 2 and 9 and tissue inhibitor of MMP*s in serum (TIMP1). MMP9/TIMP1 ratio as predictor of left atrial volume index.

•Endothelial function measured by forearm mediated vasodilatation (FMD)

•Biomarkers of (left and right) ventricular strain: NT-proBNP, troponine-T.

•Other stress-induced echocardiographic parameters: sPAP and Pv-acceleration

time, E/A and deceleration time, E/E*, Ard-Ad, Left atrial volume index (LAVI),

left ventricular mass index (LVMI)) to determine LV-DD

Study description

Background summary

The presence of left ventricle diastolic dysfunction (LV-DD), as assessed by echocardiography, can be observed at rest in more severely affected COPD patients; it has a negative impact on exercise tolerance, and may have important prognostic and potentially also therapeutic implications. Exercise-induced LV-DD is likely to precede LV-DD at rest, and may contribute to the exercise limitation which can be observed in these patients.

Study objective

The primary aim of this observational study is to determine the occurrence of exercise-induced left ventricular diastolic dysfunction (LV-DD) in symptomatic COPD patients with a normal echocardiography at rest. And, secondly, to study the relationship of exercise-induced LV-DD with baseline clinical characteristics, exercise-induced (dynamic) hyperinflation, CPET parameters and systemic inflammation.

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. Before and after exercise venous blood samples will be taken once 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- COPD patients classified according to the GOLD staging system and the criteria of the BODE index
- Informed consent
- > 18 years of age
- Male and female
- Patients able to perform a cycling test

Exclusion criteria

- Age <= 18 years of age
- Pregnancy

- Patients not able to perform a cycling test
- Patients with clinical evidence of significant cardiovascular disease (including coronary artery disease, history of myocardial infarcation, significant valvular disease, cardiomyopathy, arterial hypertension, echocardiographic presence of left ventricular systolic dysfunction)
- Patients with atrial fibrillation.
- Patients on cardiac medication (ACE inhibitors, beta-blockers, AT-II antagonists, Calcium channel blockers)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-11-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2013
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
Other	NL 40084.100.12
CCMO	NL40084.100.12