

Cardiopulmonary exercise testing and haemodynamics in patients with chronic obstructive pulmonary disease

Submission date 14/10/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/02/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Cardiopulmonary exercise testing and haemodynamics in patients with chronic obstructive pulmonary disease: an observational cross-sectional study

Study objectives

1. Gas exchange data assessed by cardiopulmonary exercise testing (CPET) will provide profound prognostic and clinically relevant data to sub-classify patients with severe chronic obstructive pulmonary disease (COPD)
2. Noninvasive cardiopulmonary exercise characteristics correlate to invasively measured haemodynamics obtained by right heart catheterisation
3. Cardiopulmonary exercise measures provide substantial prognostic properties above invasive measures and lung function abnormalities

Please note that as of 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:

Initial anticipated start date: 01/01/2009

Initial anticipated end date: 30/06/2010

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 11/02/2009: University of Greifswald ethics committee gave approval on the 20th November 2008 (ref: BB 96/08)

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Patients suffering from COPD (according to the GOLD criteria classified as stage III and IV) will undergo CPET according to a standardised exercise protocol. In addition to the previous obtained spirometric and body plethysmographic data, a number of CPET data will be investigated.

Based on this CPET data the aim of the study is to sub-classify patients into clinical and prognostic groups. The data of gas exchange during exercise might provide further insights in the exercise limiting disease related factors. The impact of the data might result in a new sub-classification of patients with severe COPD.

Depending on the investigators opinion right heart catheterisation can be applied in cases of suspected pulmonary hypertension.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Exercise variables
2. Lung function data
3. Haemodynamic measures obtained by right heart catheterisation

Primary and secondary outcomes will be assessed at the end of the study.

Secondary outcome measures

1. GOLD stage
2. Mortality

Primary and secondary outcomes will be assessed at the end of the study.

Overall study start date

01/04/2009

Completion date

30/10/2010

Eligibility

Key inclusion criteria

1. Diagnosis of COPD (according to American Thoracic Society [ATS] case definition) meeting all necessary criteria to be classified as Global Initiative for chronic Obstructive Lung Disease (GOLD) III and IV
2. Informed consent for study-related procedure
3. Stable medications for the last two weeks
4. Ability to safely perform the CPET without contraindications
5. Aged 18 - 80 years, both genders

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Existing contraindication for exercise test
2. Patients with clinically relevant congestive heart failure or other diseases which may influence the results of the study (e.g. handicaps)
3. Exacerbation of COPD within the last two weeks before CPET
4. Conditions associated with poor compliance
5. Patients who have participated in a clinical study within the last four weeks

Date of first enrolment

01/04/2009

Date of final enrolment

30/10/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Ernst Moritz Arndt University Greifswald

Greifswald

Germany

17475

Sponsor information**Organisation**

DOCxcellence GmbH (Germany)

Sponsor details

Wattstrasse 11-13
Berlin
Germany
13355

Sponsor type
Industry

Website
<http://www.docxcellence.de>

ROR
<https://ror.org/03jx7ar65>

Funder(s)

Funder type
Industry

Funder Name
DOCxcellence GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration