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

Submission date 14/10/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/11/2008	**Overall study status** Completed	
Last Edited 11/02/2009	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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)

Primary study design
Observational

Study design
Observational cross-sectional study

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s)
1. GOLD stage
2. Mortality

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/03jx7ar65

Funder(s)

Funder type
Industry

Funder Name
DOCxcellence GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration