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CardioPulmonary Exercise Testing in patients with Chronic Obstructive Pulmonary Disease

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/05/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/06/2008	Respiratory	[ ] 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
001/2008

Study information

Scientific Title

Acronym
CPET in COPD

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. Different predefined standardised exercise protocols wont show relevant differences concerning CPET results in the assessment of COPD patients

Please note that as of 23/06/2008 the funder and sponsor of this trial was changed to Ambulantes pneumologisches Zentrum GbR (Germany). Previous sponsor details can be found under the interventions section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Ernst Moritz Arndt University of Greifswald on the 31st July 2007 (ref: BB48/07).

Study design
Observational study of consecutive patients

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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 bodyplethysmographic 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.

Previous sponsor prior to 23/06/2008:
Astra Zeneca GmbH (Germany)
Tindsdaler Weg 183
Wedel, D-22880
Germany

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Exercise variables
2. Lung function data

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

Secondary outcome measures
GOLD stage, assessed at the end of the study.

Overall study start date
01/05/2008

Completion date
30/04/2009

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
01/05/2008

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Germany

Study participating centre
Ernst Moritz Arndt University Greifswald
Greifswald
Germany
17489

Sponsor information

Organisation
Ambulantes pneumologisches Zentrum GbR (Germany)

Sponsor details
c/o Dr Peter-Uwe Haase
Kleine Marktstrasse 3

Halle
Germany
D-06108

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Current funder as of 23/06/2008:

Funder Name
Ambulantes pneumologisches Zentrum GbR (Germany)

Funder Name
Previous funder:

Funder Name
Astra Zeneca 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