

CardioPulmonary Exercise Testing in patients with Chronic Obstructive Pulmonary Disease

Submission date 29/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/06/2008	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

Protocol serial number
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

Study type(s)

Screening

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(s)

1. Exercise variables
2. Lung function data

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

Key secondary outcome(s)

GOLD stage, assessed at the end of the study.

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

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

01/05/2008

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration