

# CardioPulmonary Exercise Testing in patients with Chronic Obstructive Pulmonary Disease

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