PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Effects of long-term outpatient exercise training in moderate to severe non-hypoxemic COPD patients with or without oxygen supply during the training session

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

We performed a 24 weeks structured training program with progressively increasing loads. In addition, we compared the influences of oxygen supplementation.

Brief Summary in Scientific Language

36 moderate to severe COPD patients trained supervised over 24 weeks 3 times per week and 30 minutes per session. During training, one group received oxygen-supply via nasal cannulas with a flow of 4 L x min-1, the other group got compressed air with the same flow. Lung function tests at rest (IVC, FEV1, Tiffaneau-Index) cycle-spiroergometry (peak ventilation, peak oxygen uptake, peak RER, submaximal and peak lactic acid concentrations), 6 minute walk testing and quality of life (SF 36) were conducted before, after 12 weeks, and after 24 weeks of training.

Organizational Data

- DRKS-ID: **DRKS00006077**
- Date of Registration in DRKS: **2014/04/11**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **keine Nummer , Ethics Committee of the Sports University Cologne, Germany.**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44.9 - Chronic obstructive pulmonary disease, unspecified**

Interventions/Observational Groups

- Arm 1: **Identical to the training period, one group was supplied with 4 L x min-1 oxygen via nasal cannulas (oxygen group) (training over 24 weeks 3 times per week and 30 minutes per session)**
- Arm 2: **The other group got compressed air with the same flow via nasal cannulas (air group) (training over 24 weeks 3 times per week and 30 minutes per session).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The difference of the distance achieved in the 6 minute walk test constituted the primary outcome measure, measured before the training, at midtime (after 12 weeks) and at the end of the training sessions (after 24 weeks).

Secondary Outcome

The maximum work load and the maximum oxygen uptake measured with the ergospirometry and changes at the SF36 assessment test (quality of life), each taken at the beginning, at midtime (after 12 weeks) and at the end (after 24 weeks) were the secondary outcomes.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St. Remigius Krankenhaus, 51379 Leverkusen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/09/17**
- Target Sample Size: **36**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Only patients with the diagnosis of COPD, and FEV1/FVC-ratio <0.7 after bronchodilatation and forced expiratory volume in 1 s (FEV1) <80% of predicted value were included. Stable clinical condition for at least 4 weeks and normoxemia at rest and during exercise were necessary. Until the entry in the study they should not performed regular physical training.

Exclusion criteria

Exclusion criteria were other diseases that could interfere with training (e.g. ischemic cardiac disease, musculo-skeletal problems) and psychological disorders.A criterion for fulfilling the training was participation of at least 80% of the sessions.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/02/14**

Trial Publications, Results and other documents

- Paper **Marc Spielmanns, Chantal Fuchs-Bergsma, Aurelia Winkler, Gabriele Fox, Stefan Krüger, Klaus Baum, Effects of Oxygen Supply During Training on Subjects With COPD Who Are Normoxemic at Rest and During Exercise: A Blinded Randomized Controlled Trial Respir Care, April 2015 60:4 540-548; published ahead of print December 16, 2014, doi:10.4187/respcare.03647**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*