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

Trial Description

Title

Effectivity of different oxygen therapy devices in patients with chronic lung disease in the inflight environment: oxygen cylinders vs. oxygen concentrators

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The study is used for the verification of six oxygen supplying systems (portable oxygen concentrators) in patients with chronic obstructive pulmonary disease at an altitude of 2650 m. This altitude corresponds to the cabin pressure of commercial aircrafts. Therefore, the results of the study can be transferred to the suitability of the systems tested in an inflight environment.
Thus, patients should be informed of the efficiency and performance of certain systems.
The main objective of the study is the oxygenation of the patients, as measured by blood gases 30 min after administration of oxygen through the various tested systems.

Brief Summary in Scientific Language

We selected patients with chronic obstructive lung disease (GOLD stage II/III) in a stable condition from our outpatient clinic. They were studied at the Schneefernerhaus at 2650 m. This altitude is comparable to the environment in an airplane at cruising altitude (2). The local ethics committee approved the study and written informed consent was obtained from all participants.
Baseline evaluation was performed in Munich at an altitude of 540 m and included medical history, spirometry, bodyplethysmography, oxygen saturation, heart rate and capillary blood gases from the arterialised ear lobe.
The patients were brought by cogwheel train to the altitude lab at 2650m, where they were connected to the reference oxygen system used by Lufthansa during air travel (WS120) delivering an equivalent of 2.8l O2/min via nasal cannula. After 30 min resting in supine position, blood gases were sampled from the arterialized ear lobe.
Then, each patient received oxygen via nasal cannula from one of the POCs. The oxygen delivery rate was chosen according to the results of the technical test to obtain approximately comparable delivery rates of 2.0 to 2.5 l O2/min. The devices were then changed in a random order. We obtained blood gas results and oxygen saturation data from each patient after a steady state period of 30 min with each device. To evaluate the improvement in oxygenation by the devices, each patient was also tested after exposure to room air for 30 min.

During the study period, patients were not allowed any exercise except for the walk to the bathroom, and measurements were only taken after at least 10 min of rest.

Organizational Data

- DRKS-ID: **DRKS00004257**
- Date of Registration in DRKS: **2012/07/20**
- 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.: **274/09 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
  Arm 1: Freestyle (Airsep)
  During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.
- Arm 2: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
  Arm 2: XPO2 (Invacare)
  During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.
- Arm 3: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
  Arm 3: Inogen One (Inogen)
  During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.
- Arm 4: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
  Arm 4: EverGo (Philipps).
  During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.
- Arm 5: **Patients mit COPD II/III according to GOLD are exposed in a random**

manner to six different oxygen delivering devices for 30 min:
Arm 5: Eclipse 3 (Sequal)
During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.

- Arm 6: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
Arm 6: WS120 (EMS).
During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.
- Arm 7: **Patients mit COPD II/III according to GOLD are exposed in a random manner to six different oxygen delivering devices for 30 min:**
Arm 7: room air at 2650 m
During the study, exercise was not allowed and blood gases were drawn after 30 min of exposure with each devices or room air.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Main study objective was the arterial oxygenation after 30 min of exposure with each of the tested devices or after room air at 2650 m. Oxygenation was evaluated by blood gases from the arterialised ear lobe (PaO2, partial oxygen pressure).

Secondary Outcome

Oxygen saturation (SaO2) was measured by pulse oxymetrie after 30 min of exposure with one of the tested devices or with room air at 2650 m. Carbon dioxide partial pressure (PaCO2) was assessed together with the primary outcome (PaO2) by arterial blood gas measurement.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Klinik Innenstadt, Pneumologie, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/07/01**
- Target Sample Size: **11**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

COPD Grade II / III according GOLD guidelines
stable phase of disease
living in Munich
subjective feeling that weather does influence the disease

Exclusion criteria

- concurrent severe disease (as dementia, carcinoma, right heart failure, stroke, myocardial infarction)
- continuous oxygen therapy
- high altitude fear
- reduced PaO2 < 60 mmHg
- increased PaCO2 > 50 mmHg
- patients with emphysema (intrathoracic gas volume larger 130 % predicted)

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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URL: **http://www.flugmed.org/**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/07/30**

Trial Publications, Results and other documents

** 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.*