

**Trial Description****Title****Nasal versus oro-nasal mask during High-intensity-NPPV in COPD****Trial Acronym**

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Noninvasive home mechanical has an increasing impact on treatment of chronic obstructive pulmonary disease. A recent study revealed beneficial effects of home mechanical ventilation concerning long-term survival in patients with chronic obstructive pulmonary disease if high ventilation pressures were applied. However, which type of mask should be used is unknown so far. The aim of this study is to investigate the influence of nasal versus oro-nasal masks on quality of sleep and ventilation as well as individual therapy acceptance. To address that, patients with chronic hypercapnic obstructive pulmonary disease already treated with home mechanical ventilation will be studied in two consecutive nights. The use of oronasal- vs nasal mask will be switched after one night and monitored by sleep diagnostic tools.

Brief Summary in Scientific Language

Noninvasive mechanical ventilation (NPPV) is an established treatment option in chronic hypercapnic respiratory failure with increasing user numbers. A recent study revealed beneficial effects of NPPV on long-term survival in patients with chronic obstructive pulmonary disease under high ventilation pressures with assisted-controlled ventilation mode, so called High-Intensity-NPPV (Hi-NPPV). The interface plays a crucial role in patients' therapy acceptance and ventilation quality. The role of interface and the choice of oronasal vs. nasal mask and its influence on sleep and ventilation quality in Hi-NPPV is unknown so far. In a randomised, cross-over trial patients already receiving NPPV due to chronic hypercapnic COPD will be evaluated in two consecutive nights. The interface is chosen in randomised order, oronasal vs nasal mask. In the second night, will be switched to the other interface. Polysomnographic and blood gas analysis will be performed to evaluate sleep and ventilation quality as well as individual acceptance by questionnaire. Sleep quality is the primary endpoint, comparing oronasal vs. nasal mask.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007741**
- Date of Registration in DRKS: **2015/03/17**
- 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.: **181/2014 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44.9 - Chronic obstructive pulmonary disease, unspecified**
- ICD10: **J96.11 - [generalization J96.1: Chronic respiratory failure]**

Interventions/Observational Groups

- Arm 1: **Patients receiving High-Intensity-NPPV due to chronic hypercapnic COPD will be ventilated by nasal mask interface over one night. Polysomnographic recordings as well as capillary blood gas analysis will be performed. Individual acceptance is evaluated by a questionnaire.**
- Arm 2: **Patients receiving High-Intensity-NPPV due to chronic hypercapnic COPD will be ventilated by oronasal mask interface over one night. Polysomnographic recordings as well as capillary blood gas analysis will be performed. Individual acceptance is evaluated by a questionnaire.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*



Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

sleepefficiency (as sleeptime/bedtime * 100)

Secondary Outcome

**quality of ventilation defined by alveolar ventilation represented by mean transcutaneous PCO₂ and capillary blood gases (pO₂, pCO₂);
acceptance of ventilation, evaluated by individual questionnaire;
leakages measured by individual questionnaire as well as readout of built-in software of mechanical ventilators, duration of ventilation**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Lungenklinik Köln-Merheim, Kliniken der Stadt Köln gGmbH, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/01**
- Target Sample Size: **28**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**



Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**home mechanical ventilation for at least a month ;
written consent ;
stable state of illness ;
stable blood gases (pH > 7,35 on the date) ;
underlying condition: COPD GOLD III-IV ;
High-Intensity NPPV ;
minimal IPAP of 22 mbar**

Exclusion criteria

**last hospitalization because of acute clinical deterioration during the last month;
deafness ;
mental retardation ;
lack of written consent ;
obesity (BMI > 35)**

Addresses

■ Primary Sponsor

**Lungenklinik Köln-MerheimKliniken der Stadt Köln gGmbH
Mr. Prof. Dr. med. Wolfram Windisch
Ostmerheimer Strasse 200
51109 Köln
Germany**

Telephone: **+49-(0)221-8907-18929**

Fax: **+49-(0)221-8907-8305**

E-mail: **windischw at kliniken-koeln.de**

URL: [---]*

■ Contact for Scientific Queries

**Lungenklinik MerheimKliniken der Stadt Köln gGmbH
Mr. PD Dr.med. Jan Hendrik Storre
Ostmerheimer Str. 200
51109 Köln
Germany**

Telephone: **+49221890718344**

Fax: **+4922189078305**



Contact for Scientific Queries

Lungenklinik MerheimKliniken der Stadt Köln gGmbH

Mr. PD Dr.med. Jan Hendrik Storre

Ostmerheimer Str. 200

51109 Köln

Germany

Telephone: **+49221890718344**

Fax: **+4922189078305**

E-mail: **storrej at kliniken-koeln.de**

URL: **http://www.kliniken-koeln.de/Merheim_Lungenklinik_Startseite.htm?ActiveID=1041**

■ **Contact for Public Queries**

Lungenklinik MerheimKliniken der Stadt Köln gGmbH

Mr. PD Dr.med. Jan Hendrik Storre

Ostmerheimer Str. 200

51109 Köln

Germany

Telephone: **+49221890718344**

Fax: **+4922189078305**

E-mail: **storrej at kliniken-koeln.de**

URL: **http://www.kliniken-koeln.de/Merheim_Lungenklinik_Startseite.htm?ActiveID=1041**

Sources of Monetary or Material Support

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

Lungenklinik Köln-MerheimKliniken der Stadt Köln gGmbH

Mr. Prof. Dr. med. Wolfram Windisch

Ostmerheimer Strasse 200

51109 Köln

Germany

Telephone: **+49-(0)221-8907-18929**

Fax: **+49-(0)221-8907-8305**

E-mail: **windischw at kliniken-koeln.de**

URL: **[---]***

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

VitalAire GmbH

Bornbach 2

22848 Norderstedt

Germany

Commercial (pharmaceutical industry, medical engineering industry, etc.)

VitalAire GmbH
Bornbach 2
22848 Norderstedt
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

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.