Trial Description

Title

Safety of CO2 insufflation during coloscopy in patients with chronic hypercapnia

Trial Acronym

CO2-Endo

URL of the trial

[---]*

Brief Summary in Lay Language

Analysis of safety of carbon dioxide insufflation during colorectal endoscopy for patients with chronic hypercapnia and intermittent non-invasuve home care ventilation. In guidelines for preventive medical checkup a colorectal endoscopy is recommended for all patients older than 55 years. This coloscopy is typically carried out with carbon dioxide insufflation. The analysis should investigate if using carbon dioxide insufflation there is a higher health risk for patients with chronic hypercapnia and non-invasive home care ventilation.

Brief Summary in Scientific Language

Object of the study is to investigate the safety of prevention coloscopy with CO2-Insufflation in patients with chronic hypercapnia and already established non-invasive home care ventilation. We will survey the transcutaneous-PCO2 during coloscopy, respiratory rate and oxygen saturation (with pulse oximetry) and capillary blood gas analysis before and after Coloscopy.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010784**
- Date of Registration in DRKS: **2017/03/15**
- 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**

DRKS-ID: **DRKS00010784**
Date of Registration in DRKS: **2017/03/15**
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.: **01/2017 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1184-9025**

Health condition or Problem studied

- ICD10: **J96.11 - [generalization J96.1: Chronic respiratory failure]**

Interventions/Observational Groups

- Arm 1: **Patients with chronic hypercapnia and intermittent non-invasive home care ventilation who are having a prevention coloscopy with air-insufflation**
- Arm 2: **Patients with chronic hypercapnia and intermittent non-invasive home care ventilation who are having a prevention coloscopy with cO2-insufflation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint is the difference between baseline transcutaneous PCO2 and maximum PCO2 during coloscopy.

Secondary Outcome

respiratory rate, oxygen saturation (with pulse oximetry) during examination, heart rate, amount of sedation, time of examination

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Medizinische Klinik II, Konstanz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/04/10**
- Target Sample Size: **12**
- 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

Chronic hypercapnia with intermitttent non-invasive home care ventilation (for at least 6 months)

Exclusion criteria

Acute exacerbation of respiratory situation (pH < 7,35)

Addresses

■ **Primary Sponsor**

Klinikum Konstanz, II. Medizin
Mr. Dr. med. Stephan Walterspacher
Luisenstr. 7
78464 Konstanz
Germany

Telephone: **075318011451**
Fax: **075318011453**
E-mail: **stephan.walterspacher at glkn.de**
URL: **www.lungenzentrum-bodensee.de**

■ **Contact for Scientific Queries**

Klinikum Konstanz, II. Medizin
Mr. Dr. med. Stephan Walterspacher
Luisenstr. 7
78464 Konstanz
Germany

Telephone: **075318011451**
Fax: **075318011453**
E-mail: **stephan.walterspacher at glkn.de**
URL: **www.lungenzentrum-bodensee.de**

■ **Contact for Public Queries**

Klinikum Konstanz, II. Medizin
Mr. Dr. med. Stephan Walterspacher
Luisenstr. 7
78464 Konstanz
Germany

Telephone: **075318011451**
Fax: **075318011453**
E-mail: **stephan.walterspacher at glkn.de**
URL: **www.lungenzentrum-bodensee.de**

Sources of Monetary or Material Support

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

Klinikum Konstanz, II. Medizin
Mr. Dr. med. Stephan Walterspacher
Luisenstr. 7
78464 Konstanz
Germany

Telephone: **075318011451**

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

Klinikum Konstanz, II. Medizin
Mr. Dr. med. Stephan Walterspacher
Luisenstr. 7
78464 Konstanz
Germany

Telephone: **075318011451**
Fax: **075318011453**
E-mail: **stephan.walterspacher at glkn.de**
URL: **www.lungenzentrum-bodensee.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/08/31**

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.*