Trial Description

Title

Monitoring of CO2 during percutaneous dilatational tracheostomy by transcutaneous measurement

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Percutaneous dilational tracheostomy is well established technique in intensive care medicine. Usually this technique to place a tracheostoma is performed by videobronchoscopy. The main disadvantage is the reduction of ventilation during the procedure leading to increased arterial CO2. During the trial CO2 will be measured percutaneously which should increase patient safety.

In the first part of the trial CO2 will be measured during mechanical ventilation with a tidalvolume of 6 ml/kg ideal bodyweight, in the second part with 12 ml/kg ideal body weight during intervention.

Brief Summary in Scientific Language

Transcutaneous measurement of CO2 (SenTec Digital Monitor (SenTec AG; Therwil, Switzerland)) during percutaneous dilational tracheostomy

Organizational Data

- DRKS-ID: **DRKS00011004**
- Date of Registration in DRKS: **2016/09/20**
- 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.: **101/2015 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44.1 - Chronische obstruktive Lungenkrankheit mit akuter Exazerbation, nicht näher bezeichnet**
- ICD10: **J80 - Atemnotsyndrom des Erwachsenen [ARDS]**

Interventions/Observational Groups

- Arm 1: **Observation: measurement of percutaneous CO2 during ventilation with 6 ml/kg ideal bodyweight during percutaneous dilational tracheostomy**
- Arm 2: **Intervention: measurement of percutaneous CO2 during ventilation with 12 ml/kg ideal bodyweight during percutaneous dilational tracheostomy**

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: **Basic research/physiological study**
- Assignment: **Other**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint is the measurement of the increase of CO2 by means of percutaneous measurement (SenTec Monitoring System, Switzerland). This values are validated by arterial CO2 measurement in blood gas analysis.

Secondary Outcome

Increase of CO2 depending on the size of the tube.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Pneumologische Abteilung- Intensivstation, Lungenklinik Köln-Merheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/09/30**
- Target Sample Size: **56**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

intubated patients undergoing percutaneous dilational tracheostomy with a positive endexpiratory pressure of less than 15 cmH2O; sufficient oxygenation and pH>7.20

Exclusion criteria

pH<7.20, Percutaneous dilational tracheostomy not feasible, technical impossibility of percutaneous CO2 measurement, difference of percutaneous to arterial CO2 of more than 10%

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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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/11/16**

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.*