

Trial Description

Title

Analysis of lung ventilation during prone positioning of patients with Acute Respiratory Distress Syndrome (ARDS) using Electrical Impedance Tomography (EIT)

Trial Acronym

proneEIT

URL of the trial

[---]*

Brief Summary in Lay Language

Treatment concepts of patients with severe lung failure include mechanical ventilation to improve gas exchange within the lung. Additionally, prone positioning is used in most cases. Prone positioning means the patient is rotated 180 degrees vertically for 8 to 12 hours. Studies show an improvement in oxygenation through this manoeuvre. During this manoeuvre, a variety of data is gathered to monitor lung ventilation and to assess if patient condition improves. Among this we use Electrical Impedance Tomography (EIT) to visualise lung ventilation. Up to now detailed information regarding mechanisms of improvement by prone positioning is lacking and it is unclear why some patients do not profit. Therefore we plan to analyse data, which is collected during routine treatment of patients with acute lung failure on our intensive care unit at Leipzig University Hospital, Germany. We hope to better characterize the mechanisms of prone positioning. Data is analysed using pseudonyms. Patients will not undergo additional tests or examinations since only routinely collected data (EIT measurements, clinical parameters like blood pressure, ventilator settings, oxygen fraction, lab values, performed radiological images) are analysed. Analysis and publication is done using pseudonyms, which means that identity of patients will not be revealed. The primary aim of this study is to show a redistribution of ventilation towards lung regions near the back of the patient by prone positioning.

Brief Summary in Scientific Language

Treatment concepts of patients with Acute Respiratory Distress Syndrome (ARDS) include mechanical ventilation to improve gas exchange within the lung. Additionally, prone positioning is used in most cases. Prone positioning means the patient is rotated 180 degrees vertically for 8 to 12 hours. Studies show an improvement in oxygenation through this manoeuvre. During this manoeuvre, a variety of data is gathered to monitor lung ventilation and to assess if patient condition improves. Among this we use Electrical Impedance Tomography (EIT) to visualise lung ventilation. Up to now detailed information regarding mechanisms of improvement by prone positioning is lacking and it is unclear why some patients do not profit. Therefore we plan to analyse data, which is collected during routine treatment of patients with acute lung failure on our intensive care unit at Leipzig University Hospital, Germany. We hope to better characterize the mechanisms underlying



improvement of oxygenation during prone positioning. Data is analysed using pseudonyms. Patients will not undergo additional tests or examinations since only routinely collected data (EIT measurements, clinical parameters like blood pressure, ventilator settings, oxygen fraction, lab values, performed radiological images) are analysed. Analysis and publication is performed using pseudonyms, which means that identity of patients will not be revealed. The primary aim of this study is to show a redistribution of ventilation towards dorsal lung regions by prone positioning.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009555**
- Date of Registration in DRKS: **2015/10/26**
- 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.: **083/14-10032014** , **Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **J80 - Adult respiratory distress syndrome**

Interventions/Observational Groups

- Arm 1: **Analysis of lung ventilation using electrical impedance tomography (EIT) before, during and after proning of patients with acute respiratory distress Syndrome (ARDS)**

Characteristics



- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Detection of a shift in lung ventilation towards dorsal parts of the lung during prone positioning using electric impedance tomography

Secondary Outcome

- 1. Detection of recruitment of poorly aerated lung regions by prone positioning**
- 2. Detection of an increment in the amount of aerated lung volume by prone positioning**
- 3. Proof of a correlation between quantitative computer tomography parameters (distribution of atelectasis, lung weight) and improvement of gas exchange due to prone positioning**
- 4. Proof of a minor degree of skin irritations by prone positioning and electrical impedance tomography measurements**
- 5. Comparison of electrical impedance tomography and PV-Loop (LIP) for determination of the "best PEEP"**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Anästhesiologie und Intensivtherapie, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/01**
- Target Sample Size: **30**
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(Anticipated or Actual) Date of First Enrollment: **2015/11/01**

Target Sample Size: **30**

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

- 1. Decision of the treating physicians to use prone positioning and electrical impedance tomography to detect lung ventilation**
- 2. Prone positioning of the Patient according to our hospital's standard operating procedure**
- 3. Diagnosis of ARDS according to the Berlin Definition (PaO₂/FiO₂ Ratio below 300mmHg, see ARDS Definition Task Force, JAMA 2012)**

Exclusion criteria

Patients, where electrical impedance tomography is not used

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Contact for Scientific Queries

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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 ongoing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

** 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.*