

## Trial Description

### Title

**Estimation of intrinsic PEEP by measurement of endexpiratory flow rate**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**During mechanical ventilation, the positive end-expiratory pressure inside the lungs (intrinsic PEEP) can be much higher compared to the one that is measured at the airway opening (PEEP) and displayed by the ventilator.**

**We have developed a method for calculating the pressure inside the trachea from knowledge of flow rate and the size of the endotracheal tube [1-3].**

**This method is not implemented in clinical routine but it could improve the clinical monitoring. In the current study we aim at calculating the intrinsic PEEP.**

**Therefore we compare the calculated intrinsic PEEP to the PEEP measured directly via a pressure measurement catheter and to that measured via a manoeuvre integrated in the ventilator.**

**Therefore we will measure airway pressure and flow rate in ventilated patients for 15 minutes. Via an additional side port the pressure inside the trachea will be measured directly and every 5 minutes the manoeuvre for determination of intrinsic PEEP will be performed. The study will be performed in pediatric patients since setting of ventilation parameters is difficult in those patients and therefore intrinsic PEEP plays a special role.**

**[1] Guttman J, Kessler V, Mols G, Hentschel R, Haberthür C, Geiger K. Continuous calculation of intratracheal pressure in the presence of pediatric endotracheal tubes. Crit Care Med. 2000 Apr;28(4):1018-26.**

**[2] Haberthür C, Lichtwarck-Aschoff M, Guttman J. Continuous monitoring of tracheal pressure including spot-check of endotracheal tube resistance. Technol Health Care. 2003;11(6):413-24.**

**[3] Lichtwarck-Aschoff M, Helmer A, Kawati R, Lattuada M, Sjöstrand UH, Zügel N, Guttman J, Hedenstierna G. Good short-term agreement between measured and calculated tracheal pressure. Br J Anaesth. 2003 Aug;91(2):239-48.**

### Brief Summary in Scientific Language

**In patients whose lungs are intubated and mechanically ventilated we want to test how reliable the intrinsic PEEP can be estimated by calculation [1,2,3] in comparison to direct measurement and to a measurement-maneuver.**

**[1] Guttman J, Kessler V, Mols G, Hentschel R, Haberthür C, Geiger K. Continuous calculation of intratracheal pressure in the presence of pediatric endotracheal tubes. Crit Care Med. 2000 Apr;28(4):1018-26.**

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

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**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00004963**
- Date of Registration in DRKS: **2013/05/07**
- 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.: **32/13 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Mechanically ventilated patients**

## Interventions/Observational Groups

- Arm 1: **In mechanically ventilated patients of the pediatric intensive care unit airway pressure, gas flow and tracheal pressure are measured.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**



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Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

#### Primary Outcome

**End-expiratory Intratracheal pressure during a 15 minute period, repeatedly measured directly, estimated via measurement manoeuvre and calculated.**

#### Secondary Outcome

**No secondary outcome**

#### Countries of recruitment

- DE **Germany**

#### Locations of Recruitment

- Medical Center **Universitätsklinikum, Freiburg im Breisgau**

#### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/13**
- Target Sample Size: **12**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

#### Inclusion Criteria



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

#### Additional Inclusion Criteria

**Mechanically ventilated patients of the pediatric intensive care unit, formal parental consent**

#### Exclusion criteria

**severe lung injury, terminal state of disease, missing formal consent**

#### Addresses

##### ■ Primary Sponsor

**Anästhesiologische Universitätsklinik Freiburg  
Mr. Dr. Stefan Schumann  
Hugstetter Str. 55  
79106 Freiburg  
Germany**

Telephone: **0761/27023290**

Fax: [---]\*

E-mail: **stefan.schumann at uniklinik-freiburg.de**

URL: [---]\*

##### ■ Contact for Scientific Queries

**Anästhesiologische Universitätsklinik Freiburg  
Mr. Dr. Stefan Schumann  
Hugstetter Str. 55  
79106 Freiburg  
Germany**

Telephone: **0761/27023290**

Fax: [---]\*

E-mail: **stefan.schumann at uniklinik-freiburg.de**

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### Sources of Monetary or Material Support

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

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**79106 Freiburg**

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### Status

- Recruitment Status: **Recruiting planned**
- 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.