

Trial Description

Title

Randomized comparative study for securing the airway during thoracalsurgery with double lumen tube vs endotracheal video tubs + bronchusblocker

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

We will compare to methods for single-lung ventilation: A double-lumen tube and tracheal tube with a integrated video camera combined with a directable bronchial blocker

Brief Summary in Scientific Language

For airway management during thoracic surgery with the need of single-lung ventilation (SLV) currently two methods are established: the classical double-lumen tube (DLT) as well as the EView in combination with a directable bronchial blocker. In our hospital we routinely use the DLT size 35F and 37F, both to be inserted into the right or left main bronchus. The EView is regular tracheal tube equipped with an integrated camera. A bronchus blocker inserted via the EView can thus be direct towards the intended main bronchus and inflated under visual control. Both products are CE certified and will be used with their intended specification.

Based on our experiences we hypothesize that use of an EView is associated with the following advantages: faster induction of anesthesia and recovery. Reduced airway morbidity. From the economical point of view we hypothesize that use of the EView may help to speed up process times as well as to reduce the over all costs. Till now, no randomized studies comparing the DLT and the EView are available. In order to accept or refute our hypotheses run the the presented study.

Organizational Data

- DRKS-ID: **DRKS00004412**
- Date of Registration in DRKS: **2012/10/08**
- 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.: **26/6/12 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**



Secondary IDs

Health condition or Problem studied

- Free text: **pleuraempyema**
- ICD10: **J86 - Pyothorax**

Interventions/Observational Groups

- Arm 1: **doublelumen tube RobertShaw for installation of single lung ventilation**
- Arm 2: **endotracheal videotube EView Viva sight SL plus maneuverable endobronchial blocker for installation of single lung ventilation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Airway morbidity 2 and 24 hours postoperatively (assessed by numeric analog scale (1-10)) , time from induction of anesthesia until clearance to start surgery.

Secondary Outcome

anesthesia cost per intervention, surgical conditions evaluated by the responsible surgeon

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- Medical Center **Diakoniekrankenhaus Rotenburg Wümme, Rotenburg Wümme**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/09/13**
- Target Sample Size: **50**
- 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

all Patients who have to undergo a VATS

Exclusion criteria

patients who need a thorakotomy or a VATS plus an secondary procedure

Addresses

- **Primary Sponsor**

**Diakoniekrankenhaus Rotenburg Wümme
Institut für Anästhesie und operative Intensivmedizin
Mr. Dr. med. Gerhard Lehrbach
Elise Averdieck Str 17
27356 Rotenburg
Germany**

Telephone: **04261776950**

Fax: [---]*

E-mail: **info at diako-online.de**



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E-mail: **info at diako-online.de**

URL: **www.diako-online.de**

■ **Contact for Scientific Queries**

**Diakoniekrankenhaus Rotenburg Wümme
Institut für Anästhesie und operative Intensivmedizin
Mr. Oliver Klinger
Elise Averdieck Str 17
27356 Rotenburg
Germany**

Telephone: **04261776950**

Fax: [---]*

E-mail: **o.klinger at diako-online.de**

URL: **www.diako-online.de**

■ **Contact for Public Queries**

**Diakoniekrankenhaus Rotenburg Wümme
Institut für Anästhesie und operative Intensivmedizin
Mr. Oliver Klinger
Elise Averdieck Str 17
27356 Rotenburg
Germany**

Telephone: **04261776950**

Fax: [---]*

E-mail: **o.klinger at diako-online.de**

URL: **www.diako-online.de**

■ **Collaborator, Other Address**

**Universitätsmedizin Göttingen
ZARI
Mr. PD Dr. med. Sebastian Russo
Robert-Koch-Straße 40
37099 Göttingen
Germany**

Collaborator, Other Address

**Universitätsmedizin Göttingen
ZARI
Mr. PD Dr. med. Sebastian Russo
Robert-Koch-Straße 40
37099 Göttingen
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.humanmedizin-goettingen.de**

Sources of Monetary or Material Support

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

**Diakoniekrankenhaus Rotenburg Wümme
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Fax: [---]*

E-mail: [---]*

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Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2014/02/28**

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.