Trial Description

Title

Intubation using VieScope, video laryngoscopy and conventional laryngoscopy in simulated difficult airway - a randomized, controlled model study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Endotracheal intubation continues to be the gold standard of airway management in emergency situations. This is primarily done using direct laryngoscopy, but is increasingly being supplemented by video laryngoscopy and in some cases even replaced. A dreaded situation in airway management is the difficult intubation due to anatomical conditions.
A unknown difficult airways can thus be a great challenge for the treating staff and a rapidly life-threatening situation for the patient.

The VieScope® (Androit Surgical LCCC, Oklahoma City, USA) represents a new type of laryngoscopy, which, according to the manufacturer, leads to optimal illumination of the airways.
The VieScope has not yet been examined in any clinical study. There are therefore no published data on the safety of use and no comparison with established methods of airway management such as video laryngoscopy or direct laryngoscopy.

Brief Summary in Scientific Language

Is the intubation and thus airway securing with VieScope safe (success rate) and efficient (time duration) compared to conventional video laryngoscopy (GlideScope) and direct laryngoscopy in simulated difficult airway?

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

No

Description IPD sharing plan

all data will be published

Organizational Data

- DRKS-ID: **DRKS00024968**
- Date of Registration in DRKS: **2021/03/31**
- 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.: **20-1475_2 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- Free text: **DIFFICULTAIRWAY**

Interventions/Observational Groups

- Arm 1: **endotracheal intubation with VieScope**
- Arm 2: **endotracheal intubation with Videolaryngoscopy (Glidescope)**
- Arm 3: **endotracheal intubation with conventional endotracheal Intubation (Macintosh)**

Characteristics

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

Primary Outcome

1. Tube position: tracheal, bronchial, oesophageal (primary endpoint),

immediately after Intubation, validated by insufflation of the test lung

Secondary Outcome

2. Correct tube position for the first intubation - "first pass" (secondary endpoint)
3. Time to Intubation (Secondary Endpoint)
4. Time to first ventilation (secondary endpoint)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Uniklinik Köln, Köln**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2021/04/01**
- Target Sample Size: **35**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

• male or female volunteers
• medical healthcare professionals
• Age between 18 and 65 years
• Prior written consent following written and verbal information from an investigator

Exclusion criteria

• male or female volunteers
• medical healthcare professionals
• Age between 18 and 65 years
• Prior written consent following written and verbal information from an

investigator

Addresses

■ **Primary Sponsor**

Uniklinik Köln - Anästhesie und operative Intensivmedizin
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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)**

Uniklinik Köln - Klinik für Anästhesiologie und Operative Intensivmedizin
Mr. Dr.med. Hannes Ecker

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**

** 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.*