

## Trial Description

### Title

**Application study of ultrasound-guided regional anesthesia and puncture procedures on a phantom gel model**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The use of ultrasound-guided procedures for regional anesthesia and endovascular punctures has increased during the recent years. We evaluate the influence of a new needle-tracking technique in real-time ultrasonography imaging on the duration of puncture procedures. Anesthesiologists with different levels of education place needles for regional anesthesia and vascular access in a ultrasound-phantom. Candidates are recruited from the medical staff of the Clinic of Anesthesiology and Intensive Care.**

### Brief Summary in Scientific Language

**The use of ultrasound-guided procedures for regional anesthesia and vascular access has increased during the recent years. A new navigation needle-tracking technique is able to visualize the needle in real-time ultrasonography imaging. In contrast to the standard ultrasound-technique, the exact position and movements of the needle can always be displayed. We test the hypothesis that using a new ultrasound technique reduces the duration for vascular access and regional anesthesia. Primary endpoint is the time required for correct needle positioning conducted on a training phantom. Candidates are recruited from the medical staff of the Clinic of Anesthesiology and Intensive Care of the University Hospital of Cologne having different experience in ultrasound-guided regional anesthesia procedures.**

## Organizational Data

- DRKS-ID: **DRKS00005581**
- Date of Registration in DRKS: **2013/12/10**
- 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.: **13-303 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**



## Secondary IDs

## Health condition or Problem studied

- Free text: **ultrasound-guided anesthesia and vascular access**

## Interventions/Observational Groups

- Arm 1: **Candidates will perform ultrasound-guided punctures for regional anesthesia and vascular access.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Single arm study**
- Blinding: [---]\*
- 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

**Time required for correct needle positioning**

## Secondary Outcome

**satisfaction with the technique, questionnaire validation**

## Countries of recruitment

- **DE Germany**



## Locations of Recruitment

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/20**
- 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: **65 Years**

## Additional Inclusion Criteria

**medical staff of the Clinic of Anesthesiology and Intensive Care**

## Exclusion criteria

**see inclusion criteria**

## Addresses

### ■ Primary Sponsor

**Klinik für Anästhesiologie und Operative Intensivmedizin, Uniklinik Köln  
50937 Köln  
Germany**

Telephone: [---]\*

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### ■ Contact for Scientific Queries

**Klinik für Anästhesiologie und Operative Intensivmedizin**

### Contact for Scientific Queries

**Klinik für Anästhesiologie und Operative Intensivmedizin**

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#### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

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

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URL: [---]\*

## Status

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

#### ■ Study Closing (LPLV): **2014/01/31**

## Trial Publications, Results and other documents

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**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

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*\* 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.*