



## Trial Description

### Title

**Continuous intraoperative neuromonitoring during neck surgery - a prospective, randomized trial**

### Trial Acronym

**IKONA CIONM**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The clinical investigation shall be conducted to examine a new monitoring system for recurrent laryngeal nerve monitoring during thyroid and parathyroid surgery.**

### Brief Summary in Scientific Language

**Recurrent laryngeal nerve palsy is a dreaded complication in thyroid surgery. Despite the improved identification of the nerve with intermittent nerve stimulation and monitoring, a decrease of nerve palsy rates could not yet be shown.**

**The system under evaluation has been newly developed for continuous intraoperative neuromonitoring. The system comprises a stimulation electrode that has been designed for vagus nerve stimulation.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00000447**
- Date of Registration in DRKS: **2010/06/21**
- 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.: **460/2009MPG1 , Ethik-Kommission an der**



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**Medizinischen Fakultät der Eberhard-Karls-Universität und am  
Universitätsklinikum Tübingen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **E04 - Other nontoxic goitre**
- ICD10: **C73 - Malignant neoplasm of thyroid gland**

## Interventions/Observational Groups

- Arm 1: **standard elektrode V3, Inomed GmbH**
- Arm 2: **newly developed stimulation electrode IKS-1 ("Saxophon"-Elektrode)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

## Primary Outcome



## Safety and effectiveness of the new svagus nerve stimulation electrode

### Secondary Outcome

**Reduction of clinical complications in thyroid surgery by continuous interoperative neuromonitoring (CIONM)**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2010/07/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **21 Years**
- Maximum Age: **99 Years**

### Additional Inclusion Criteria

- 1. planned, elective neck surgery**
- 2. ability of the patient to give informed consent**

### Exclusion criteria

- 1. Preexisting palsy of the recurrent laryngeal nerve**
- 2. Patients suffering from severe cardiac arrhythmia (tachycardic/ bradycardic heart rhythm with hemodynamic instability)**
- 3. Patients with a cardiac pacemaker**
- 4. Pregnancy/ breast feeding mums/patients**
- 5. Missing informed consent/  
Patient is unable to provide informed consent**

## Addresses

### ■ Primary Sponsor

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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**BMBF Projekt IKONA, Förderkennzeichen 01EZ0725**

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E-mail: [---]\*

URL: [---]\*

## Status

- Recruitment Status: **Recruiting ongoing**
- 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.