

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Treatment of supraventricular tachycardia with Cryo-Ablation under ICE (intracardiac echocardiography) navigation**

### Trial Acronym

**ICE-SVT**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

[---]\*

### Brief Summary in Scientific Language

**Supraventricular tachycardias do not limit the life expectancy of the affected patients. The Catheter-Ablation mostly eliminates the symptoms of These patients. The Exposition to fluoroscopy may lead to so-called stochastic Radiation damage. The aim of the study is to investigate the combination of a safe Ablation type with a zero- or near-zero fluoroscopy Navigation technique.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00011360**
- Date of Registration in DRKS: **2016/12/14**
- 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.: **86/16 , Ethikkommission der Medizinischen**

DRKS-ID: **DRKS00011360**

Date of Registration in DRKS: **2016/12/14**

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**

**Fakultät der Otto-von-Guericke-Universität Magdeburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **I47.1 - Supraventricular tachycardia**

## Interventions/Observational Groups

- Arm 1: **Catheterablation under fluoroscopic control is the first choice treatment of supraventricular tachycardias. We'd like to investigate the combination of intravascular echocardiography (ICE) Navigation and Cryo-Ablation in Patients with presumed supraventricular Tachykardias.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

## Primary Outcome

**The aim of the study is to observe and analyse the fluoroscopic time and radiation dose (both parameters are routinely documented for every electrophysiologic study) during Cryothermal-ablation of atrio-ventricular-node-reentry-tachycardia under intracardiac-echocardiography-Navigation.**

### Secondary Outcome

**Secondary endpoint of the study is to assess and analyse the success rate of the cryothermal-ablation for treatment of atrioventricular-node-reentry-tachycardia under intracardiac-echocardiography-Navigation. Success is defined as clinical freedom from arrhythmia after 3 and 12 months.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- **University Medical Center Kardiologie, Magdeburg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/10/28**
- 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: **no maximum age**

### Additional Inclusion Criteria

**documented or clinical probably supraventricular tachycardia**

### Exclusion criteria

**documented or clinical probably ventricular tachycardia, atrial fibrillation, atrial flutter, fever, acute infection, acute or subacute leg vein thrombosis or pulmonary embolism, pregnancy**

**documented or clinical probably ventricular tachycardia, atrial fibrillation, atrial flutter, fever, acute infection, acute or subacute leg vein thrombosis or pulmonary embolism, pregnancy**

## Addresses

### ■ Primary Sponsor

**Universitätsklinikum Magdeburg  
Leipziger Str. 44  
39120 Magdeburg  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [www.med.uni-magdeburg.de](http://www.med.uni-magdeburg.de)

### ■ Contact for Scientific Queries

**Universitätsklinikum Magdeburg Klinik für Kardiologie und Angiologie  
Mr. Dr. med. Blerim Luani  
Leipzigerstr. 44  
39120 Magdeburg  
Germany**

Telephone: **0391 67 15 206**

Fax: **0391 67 15 211**

E-mail: [blerim.luani at med.ovgu.de](mailto:blerim.luani@med.ovgu.de)

URL: <http://www.kkar.ovgu.de/>

### ■ Contact for Public Queries

**Universitätsklinikum Magdeburg Klinik für Kardiologie und Angiologie  
Mr. Dr. med. Blerim Luani  
Leipzigerstr. 44  
39120 Magdeburg  
Germany**

Telephone: **0391 67 15 206**

Fax: **0391 67 15 211**

E-mail: [blerim.luani at med.ovgu.de](mailto:blerim.luani@med.ovgu.de)

URL: [---]\*

## Sources of Monetary or Material Support

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

**Universitätsklinikum Magdeburg**

DRKS-ID: **DRKS00011360**

Date of Registration in DRKS: **2016/12/14**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

---

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

**Universitätsklinikum Magdeburg**

**Leipziger Str. 44**

**39120 Magdeburg**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.med.uni-magdeburg.de**

## 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.