## Trial Description

### Title

**Comparison of the "anterior-superior tympanoplasty" and the "U-spring tympanoplasty" for the reconstruction of anterior and subtotal defects of the tympanic membrane**

### Trial Acronym

**[---]***

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**[---]***

### Brief Summary in Scientific Language

**The most effective surgical technique for the reconstruction of anterior and subtotal defects of the tympanic membrane is still a matter of debate. Posterior defects can be reconstructed with a success rate of around 95%. In contrast, success rates of anterior defects are reported as low as 67%. Published data on the outcomes after tympanoplasty usually rely on retrospective analysis of single methods. The techniques used in this study, i.e. the “anterior-superior tympanoplasty” and the “U-spring tympanoplasty” have not been described yet in detail.**
**Accordingly, the main goal of our prospective study is to compare both tympanoplasty techniques for the closure of anterior and subtotal defects of the tympanic membrane and evaluate their audiological outcome.**

## Organizational Data

- DRKS-ID: **DRKS00014863**
- Date of Registration in DRKS: **2018/06/08**
- 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.: **51_18 B , Ethik-Kommission der Friedrich-Alexander-Universität Erlangen-Nürnberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **H66.9 - Otitis media, unspecified**
- ICD10: **H73.8 - Other specified disorders of tympanic membrane**

## Interventions/Observational Groups

- Arm 1: **anterior- superior tympanoplasty**
- Arm 2: **U-spring tympanoplasty**

## 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: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**The primary endpoint of the study is the successfull reconstruction of anterior and subtotal defects of the tympanic Membrane and the audiological outcome (otoscopic and audiometric examination) 6, 12 and 24 monnths after surgery.**

### Secondary Outcome

**[---]***

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **HNO-Klinik, Erlangen**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/18**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**- All patients 18 yrs of a age or older that exhibit an anterior or subtotal defect of the tympanic membrane. Additionally, the ossicular chain is intakt. All patients referred to the ENT clinic at the university of Erlangen.**

### Exclusion criteria

**Patients that refuse to give their approval to participate in the study and those who suffer from diseases of the cartilage and/or skin.**

## Addresses

- **Primary Sponsor**

  **HNO Uniklinik Erlangen**
  **Waldstrasse 1**
  **91341 Erlangen**
  **Germany**

  Telephone: **091318546574**
  Fax: **[---]***
  E-mail: **antoniu-oreste.gostian at uk-erlangen.de**
  URL: **[---]***
- **Contact for Scientific Queries**

**Contact for Scientific Queries**

**HNO Uniklinik Erlangen**
**Mr. PD Antoniu-Oreste Gostian**
**Waldstrasse 1**
**91054 Erlangen**
**Germany**

Telephone: **004991318546574**
Fax: **[---]***
E-mail: **antoniu-oreste.gostian at uk-erlangen.de**
URL: **[---]***

- **Contact for Public Queries**

**HNO Uniklinik Erlangen**
**Mr. PD Antoniu-Oreste Gostian**
**Waldstrasse 1**
**91054 Erlangen**
**Germany**

Telephone: **004991318546574**
Fax: **[---]***
E-mail: **antoniu-oreste.gostian at uk-erlangen.de**
URL: **[---]***

## Sources of Monetary or Material Support

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

**HNO-Universitätsklinik Erlangen**
**Mr. Pd Antoniu - Oreste Gostian**
**Waldstrasse 1**
**91054 Erlangen**
**Germany**

Telephone: **004991318546574**
Fax: **[---]***
E-mail: **antoniu-oreste.gostian at uk-erlangen.de**
URL: **[---]***

## Status

- Recruitment Status: **Recruiting planned**
- 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.*