Trial Description

Title

Prospective, randomized clinical trial for the comparison of the voice protheses Phonax® and Provox II®

Trial Acronym

Phonax

URL of the trial

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Brief Summary in Lay Language

Randomized prospectiv clinical trial for the comparison of twp voice protheses: Phonax and Provox II.
After a complete laryngectomie (removal of the larynx) the patient often receives a voice protheses for voice rehabilitation. This trial will compare the two above mentioned protheses with respect to their functioning, patient satisfaction as well as with respect to potential complications.

Brief Summary in Scientific Language

This trial willcompare the most frequently used voice protheses in Europe, Provox II (ATOS Medical GmbH) with the voice prothesis Phonax with respect to their duration of stay, functionality, compliation rate and handling with respect to placement and replacement of the protheses.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006176**
- Date of Registration in DRKS: **2014/05/21**
- 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**
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(leading) Ethics Committee Nr.: **022/14-ff , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **C32.9 - Malignant neoplasm: Larynx, unspecified**
- ICD10: **Z90 - Acquired absence of organs, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **use of Phonax(R) voice prothesis**
- Arm 2: **use of Provox II(R) voice prothesis**

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: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Number of voice protheses per year in the course of a three year follow-up with a maximum duration of stay of one year per prothesis.

Secondary Outcome

•3 year loco-regional control (staging, recurrence of tumor)
•symptomscore related to breathing-/ speaking- and swallowing ability
•complication rate related to the protheses /mediaclly documented (inspection of tracheostom, tracheoskopy with optics, way of insuffiziency, promblems with the fistula) during the 3 years of follow-up.
•funktioning of the voice protheses: PLTT (Post Laryngektomie Telefon Test), VHI (Voice Handicap Index), sound holding period 12, 24 and 36 months post surgery
•biofilm-parameterp: analysis of the voice prothesis after explantation by swab and microbiological analyses
•patient's quality of life (questionaires) 12, 24 and 36 monaths post surgery
•primary placement of the voice prothesis (questionaire for the surgeon)
•replacement of the voice prothesis (questionaire for the physician)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Hals-, Nasen-, Ohrenheilkunde, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/01**
- Target Sample Size: **58**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

•histologically verified, primary resectable Larynx/Hypopharynxcarcinoma
•indikation for laryngectomy with primary creation of a tracheo esophageal fistula

•planned curative resection (R0-resection)
•stage II/IV A ollowing UICC (without T1)
•low to slightly enhanced risk of anesthesia
•adequate bone marrow-, liver- and kindneyfunction
•Karnofsky-Index ≥70%
•Age 18-80 Years
•written informed consent

Exclusion criteria

•tumorspezifc pre-treatment (chemotherapy, radiation therapy)
•Metachrone or synchrone malignom (exception: basaliom or low-risk prostatecarcinoma) [In case of a controlled tumor at a different location with a treatment free intervall of more than 5 years, inclusion might be possible after consultation of the co-ordinating investigator]
•life expectancy < 6 months
•acute infection or fever
•anamnestic HIV-infection or othe immune suppression
•serious cardio-pulmonary concomittant disease (heart insufficiency grade III and IV following NYHA scale, myocardial infarction, angina pectoris, respiratoric insufficiency serious Asthma bronchiale, COPD (FEV1 <35%))
•chronic disease with permanent therapy (uncontrolled Diabetes, rheumatoide Arthritis) particularly steroid therapy
•other concomittant diseases, which exclude the patient from the trial from the perspective of the trial physician
•analphabetism
•intolerance regarding the materials of the voice protheses
•experienced low patient's compliance
•regular follow-up impossible (e. g. patient lives outside of Germany)
•lack of or patial legal capcity of the patient
•participation in another clinical trial or application of a not yet registered substancewithin 30 days before trial start
•pregnant or nursing
•fertile female patients (< 2 years after the last spontaneous menstruation) without effective contraception (implants, injections, oral contraceptives, intrauterine devices, vasectomized partner)

Addresses

■ **Primary Sponsor**

Klinik und Poliklinik für Hals-, Nasen-, Ohrenheilkunde Leipzig
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URL: **[---]***

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Contact for Scientific Queries

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- **Contact for Public Queries**

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URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

HEIMOMED GmbH & Co. KG
50170 Kerpen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2018/07/11**

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.