Trial Description

Title

Multicentre trial on immediate rehabilitation using HME-filters after a total laryngectomy

Trial Acronym

HME-Filter Sofort ReHa

URL of the trial

[---]*

Brief Summary in Lay Language

This trial will analyze whether the strict use of HME-filters (heat and moisture exchangers / artificial nose) in patients directly after complete laryngectomy (removal of the larynx) is able to improve patient care in the immediate post operative phase in comparison to the standard treatment using external nebulizers.

Included will be patients after a complete laryngectmoy in the immediate post operative phase.

As a result of the surgery, the airways from the mouth, nose, and esophagus are separated. The laryngectomee breathes through an opening in the neck, a stoma. Thus the moisturizing and warming effect of the nose on the inhaled air is abolished and the air breathed in through the stoma is colder and drier than usual, potentially leading to irritations of the mucosa of the trachea or bronchii. This might result in enhanced mucus production, incrustations, coughing attacks and possibly to a reduced lung function.

Pilot trials showed a temperature increase of 9°C and a moisture rise of 20% with respect to the inhaled air breathed through an HME-filter in comparison to breathing through the open tracheostoma.

This impovement of the inhaled air might result in an improved lung function.

Dircetly befor the laryngectomy, patients participating in this clinical trial will be randomly assigned to a treatment group (HME-filter use versus external nebulizers without HME-filters). During their in hospital stay of 10 days, the patients will be treated according to the randomization result and bronchio pulmonary symptoms (frequency of aspiration, frequency of coughing attacks, mucus production) will be recorded in patient diaries. Additionally, objective parameters of lung function will be determined using lung function tests.

The occurence of bronchio-pulmonary symptoms and the lung function test results compared between the treatment groups will be used to answer the question, whether the moisturizing and warming effect of the HME-filter is able to improve bronchio-pulmonary function in comparison to the standard treatment using external nebulizers.

Brief Summary in Scientific Language

This trial will analyze whether the strict use of HME-filters (heat and moisture exchangers / artificial nose) in patients directly after complete laryngectomy (removal of the larynx) is able to improve patient care in the immediate post operative phase in comparison to the standard treatment using external nebulizers.

Included will be patients after a complete laryngectmoy in the immediate post operative phase.

As a result of the surgery, the airways from the mouth, nose, and esophagus are separated. The laryngectomee breathes through an opening in the neck, a stoma. Thus the moisturizing and warming effect of the nose on the inhaled air is abolished and the air breathed in through the stoma is colder and drier than usual, potentially leading to irritations of the mucosa of the trachea or bronchii. This might result in enhanced mucus production, incrustations, coughing attacks and possibly to a reduced lung function.

Pilot trials showed a temperature increase of 9°C and a moisture rise of 20% with respect to the inhaled air breathed through an HME-filter in comparison to breathing through the open tracheostoma.

This impovement of the inhaled air might result in an improved lung function.

Dircetly befor the laryngectomy, patients participating in this clinical trial will be randomly assigned to a treatment group (HME-filter use versus external nebulizers without HME-filters). During their in hospital stay of 10 days, the patients will be treated according to the randomization result and bronchio pulmonary symptoms (frequency of aspiration, frequency of coughing attacks, mucus production) will be recorded in patient diaries. Additionally, objective parameters of lung function will be determined using lung function tests.

The occurence of bronchio-pulmonary symptoms and the lung function test results compared between the treatment groups will be used to answer the question, whether the moisturizing and warming effect of the HME-filter is able to improve bronchio-pulmonary function in comparison to the standard treatment using external nebulizers.

Organizational Data

- DRKS-ID: **DRKS00000379**
- Date of Registration in DRKS: **2010/03/24**
- 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.: **256/09 , Ethik-Kommission der Universität Ulm**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1114-5122**
-

Sponsor-ID: **HME-Filter Sofort ReHa (Bezeichnung des Auftraggebers)**

Health condition or Problem studied

- ICD10: **Z93.0 - Tracheostomy status**
- ICD10: **Z90.0 - Acquired absence of part of head and neck**

Interventions/Observational Groups

- Arm 1: **The day after laryngectomy the patients will be supplied with HME-Filters, which will be used until discharge from hospital. The filter will be changed by the patient regularly.**

  The filters used will be from Atos Medical GmbH: PROVOX XtraHME.
- Arm 2: **After laryngectomy the patients will be treated by standard care procedures using external nebulizers.**

  This treatment arm does not receive a trial specific therapy. The only additional effort is the data-keeping.

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): **[---]***

Primary Outcome

Primary endpoint of the clinical trial is the bronchial mucus production as measured by the number of tracheobronchial aspirations documented on the patient's diary over the course of the first ten post operative days.

Secondary Outcome

cough frequency, determined from the patients's diary over the course of the first ten post operative days || bronchial mucus production, determined from the

patients's diary over the course of the first ten post operative days || lung function at day 3 and 10 post surgery.

Determined will be vital capacity, FEV1 and FIV1, PEF and PIF, MEF50 and MIF50 and total lung capacity (TLC) resulting from a lung function test || direct costs of treatment, determined from a questionnaire (part of the CRF) over the course of the first ten post operative days || therapy compliance of the patient, the use of HME-filters as well as of other filter systems will be recorded in the CRF over the course of the ten first post operative days. || patient's satisfaction, determined from the patients's diary over the course of the first ten post operative days

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/03/10**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- patient following complete laryngectomy immediately after surgery
- age >= 18 years
- written informed consent

Exclusion criteria

- bleedings of the lower respiratory tract (lung, bronchii, trachea)
- inability to change the HME-filter by themselves (e. g. hand or arm problems, coordination deficits)
- lacking compliance

- participation in other interventional trials
- physical, mental or other inability to supply required information

Addresses

■ **Primary Sponsor**

Atos Medical GmbH
Mr. Reinhold Halisch
Müllheimerstrasse 3-7
D-53480 Troisdorf
Germany

Telephone: **02241 1493-0**
Fax: **02241 1493-72**
E-mail: **Reinhold.Halisch at atosmedical.com**
URL: **http://www.atosmedical.de/**

■ **Contact for Scientific Queries**

Zentrum für klinische Studien Leipzig - KKS
Ms. Dr. rer. nat. Petra Neuhaus
Haertelstr. 16-18
04107 Leipzig
Germany

Telephone: **0341 97 16255**
Fax: **0341 97 16189**
E-mail: **petra.neuhaus at zks.uni-leipzig.de**
URL: **http://www.zks.uni-leipzig.de**

■ **Contact for Public Queries**

Bundeswehrkrankenhaus Ulm, HNO-Abteilung
Mr. Dr. med. Kai J. Lorenz
Oberer Eselsberg 40
89081 Ulm
Germany

Telephone: **0731 1710 1503**
Fax: **0731 525 767**
E-mail: **kai.lorenz at extern.uni-ulm.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Atos Medical GmbH
Mr. Reinhold Halisch

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

Atos Medical GmbH
Mr. Reinhold Halisch
Müllheimerstrasse 3-7
53480 Troisdorf
Germany

Telephone: **02241 1493-0**
Fax: **02241 1493-72**
E-mail: **Reinhold.Halisch at atosmedical.com**
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/09/30**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*