Trial Description

Title

Occlusive wound healing after endonasal endoscopic sinus surgery – a prospective randomized trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The main goal of the study is to compare wound healing after sinus surgery with occlusion of the nose and with standard open aftercare. We want to investigate if occlusive wound healing is quicker than open wound healing. The state of wound healing is examined 2, 3, 4, 12 weeks and 1 year after surgery.The duration of the cleaning of the nose and the size of the frontal and maxillary sinus ostium are also compared.
Aftercare after sinus surgery is necessary and important and improves the outcome. The aim of the aftercare is to improve wound healing and early regeneration of epithelium, to reduce local inflammation and patient symptoms in the early postsurgical phase. Usually the nose and sinuses are cleaned with instruments during the first days after surgery. Occlusion of the nose, e.g. temporary closure of the nose with a tape, is relatively new. It is recommended, as occlusion of wounds ensures a moist wound environment, which has a positive effect on wound healing. Occlusion prevents drying-out of superficial tissue layers which leads to superficial necrosis and drying-up of wound fluids. After sinus surgery study participants receive medical treatment for their sinus disease. They receive a steroid nasal spray and are asked to perform nasal douches. This treatment is independent of the study. Depending on which group the participants are randomized to, the nose will be cleaned regularly or a special tape is applied to the nose for 2 weeks. 2, 3, 4, 12 weeks and 1 year after surgery the wound healing is evaluated by the ENT surgeon at the hospital. In addition participants are asked to complete a questionnaire regarding their health condition.

Brief Summary in Scientific Language

The aim of the randomized study is to compare the conventional postoperative aftercare after sinus surgery with daily debridement of the nose with occlusion of the nose. the following parameters are compared in a two armed study design: dynamics of wound healing, effort of aftercare for patient and surgeon, comfort for the patient. After endoscopic sinus surgery patients receive medical treatment independent of the group they are randomized to according to current guidelines. To achieve a homogenous group, only patients with chronic rhinosinusitis with nasal polyps are included in the study.They receive the following medical treatment:
- topical nasal steroid (2 x 2 puffs daily) for 12 months
- nasal douches 3 x daily

- antibiotics (cephalosoprin i.v. preoperatively, Doxycyclin 100 mg OD, if allergic Cotrim forte 2 x 960 mg for 10 days)
- systemic steroids (Prednisolon 20 for 10 days)
Patients within the first study arm are asked to occlude the nose for 2 weeks 24 hours a day with a special tape. The tape is temporarily removed to use the steroid spray and for nasal douching. After temporary removal of the tape the nose is cleaned with instruments 2, 3 and 4 weeks after surgery by the ENT surgeon. In Patients in the second study arm the nasal cavity is left open. The nose is debrided daily during the inpatient stay . Afterwards the nose is cleaned with instruments 2, 3 and 4 weeks after surgery by the ENT surgeon.
Primary outcome:
- sinunasal wound healing 2 weeks postoperatively according to endoscopic score by Valentine 2010.
Occlusion of the nose will lead to a faster wound healing after endoscopic sinus surgery.
Secondary outcome:
- Occlusive wound healing is more comfortable for the patient (measured by VAS)
- sinunasal wound healing after 2, 3, 4, 12 weeks and 1 year after surgery is improved according to endoscopic score by Valentine 2010
- the duration of each aftercare visit is reduced
- the maxillary and frontal sinus neo-ostium is greater with occlusion

Organizational Data

- DRKS-ID: **DRKS00009790**
- Date of Registration in DRKS: **2015/12/29**
- 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.: **332/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J32.4 - Chronic pansinusitis**

Interventions/Observational Groups

- Arm 1: **- topical nasal steroid (2 x 2 puffs daily) for 12 months**
  - nasal douches 3 x daily
  - antibiotics (cephalosoprin i.v. preoperatively, Doxycyclin 100 mg OD, if

allergic Cotrim forte 2 x 960 mg for 10 days)
- systemic steroids (Prednisolon 20 for 10 days)
Occlusion of the nose for 2 weeks 24 hours a day. The tape is temporarily removed to use the steroid spray and for nasal douching. After temporary removal of the tape the nose is cleaned with instruments 2, 3 and 4 weeks after surgery by the ENT surgeon.

- Arm 2: **- topical nasal steroid (2 x 2 puffs daily) for 12 months**
  - nasal douches 3 x daily
  - antibiotics (cephalosoprin i.v. preoperatively, Doxycyclin 100 mg OD, if allergic Cotrim forte 2 x 960 mg for 10 days)
  - systemic steroids (Prednisolon 20 for 10 days)
  The nasal cavity is left open. The nose is cleaned daily during the inpatient stay . Afterwards the nose is cleaned with instruments 2, 3 and 4 weeks after surgery by the ENT surgeon.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Primary outcome: sinunasal wound healing 2 weeks postoperatively according to endoscopic score by Valentine 2010.
Hypothesis: Occlusion of the nose will lead to a faster wound healing after endoscopic sinus surgery.

Secondary Outcome

Secondary outcome:
- patient comfort measured by VAS 2, 3, 4, 12 weeks and 1 year postoperatively
- sinunasal wound healing after 3, 4, 12 weeks and 1 year after surgery according to endoscopic score by Valentine 2010
- the duration of each aftercare visit in minutes 2, 3, 4 weeks postoperatively
-size of the maxillary and frontal sinus neo-ostium in mm 3 months and 1 year postoperatively meassured with 3 mm suction instrument

Countries of recruitment

- DE **Germany**
- CZ **Czech Republic**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**
- University Medical Center **Greifswald**
- University Medical Center **Regensburg**
- Medical Center **Karlsruhe**
- Doctor's Practice **Dr. Andy Weidner, Bad Urach**
- University Medical Center **Ostrava, Tschechische Republik**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/12/10**
- Target Sample Size: **174**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

- Age >/= 18 years
- bilateral endonasal endoscopic sinus surgery: maxillary sinusotomy, anterior and posterior ethmoidectomy, frontal sinus drainage Draf IIa
- chronic rhinosinusitis with nasal polyps not responding to medical treatment (at least topical steroids for 6 weeks, nasal douches, antibiotics for 3 weeks if indicated, systemic steroids if indicated)
- informed consent
- compliance with the study protocol

Exclusion criteria

- no consent
- diseases that affect wound healing (AIDS, cystic fibrosis, immune deficiency, neutropenia)
- coagulation disorders or anticoagulants up to 7 days preoperatively
- indications for sinus surgery other than CRSwNP

Addresses

■ **Primary Sponsor**

HNO-KlinikUniklinik Freiburg
Killianstr. 5
79106 Freiburg
Germany

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

■ **Contact for Scientific Queries**

HNO-KlinikUniklinik Freiburg
Ms. Dr. Tanja Hildenbrand
Killianstr. 5
79106 Freiburg
Germany

Telephone: **0761/27042010**
Fax: **[---]***
E-mail: **tanja.hildenbrand at uniklinik-freiburg.de**
URL: **[---]***

■ **Contact for Public Queries**

HNO-KlinikUniklinik Freiburg
Ms. Dr. Tanja Hildenbrand
Killianstr. 5
79106 Freiburg
Germany

Telephone: **0761/27042010**
Fax: **[---]***
E-mail: **tanja.hildenbrand at uniklinik-freiburg.de**
URL: **[---]***

Sources of Monetary or Material Support

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

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HNO-KlinikUniklinik Freiburg
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79106 Freiburg
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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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