



Trial Description

Title

Examination of head and neck tissue specimens with optical coherence tomography and narrow band imaging

Trial Acronym

n/a

URL of the trial

<http://n/a>

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

In the recent years there was a continuous development in the imaging techniques for visualization of head and neck anatomy and pathology. New optical techniques like Optical Coherence Tomography (OCT) and Narrow Band Imaging (NBI) had substantial progress and are now established in certain medical sectors. Since it was developed in 1991 OCT became a routine part for the examination of the retina (Huang 1991, Massin 2006). With technical modifications it is also possible to use OCT for the examination of the normal anatomy, for example lymphatic drainage. NBI is used for evaluation of mucosal alterations for example in gastroenterology or urology (Boeriu 2015, Casey 2015). During the last years the use of NBI was also evaluated for head and neck disease showing advantages in the diagnosis of laryngeal papillomatosis (Dippold 2015). Possible use for head and neck surgeons are therefore examination of the anatomy and pathological influences (inflammation, neoplasm). The use in the head and neck area was restricted by the size of the probes. The development of more and more smaller probes now enables further examinations. Analysis of picture quality and feasibility are aim of this study.

Organizational Data

- DRKS-ID: **DRKS00009220**
- Date of Registration in DRKS: **2015/08/12**
- 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.: **294/15** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Neoplasms and malignancies of the upper airway, the nose, the paranasal sinuses, external ear channel, middle ear and head and neck skin**

Interventions/Observational Groups

- Arm 1: **Patients with scheduled surgical procedures are chosen. Informed consent is obtained. A small part of the tissue specimen which is resected anyway are examined with different OCT- and NBI-probes. Pictures are analyzed concerning quality. The largest part of the tissue specimen is brought to histopathologic examination.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Same imaging quality with new OCT- and NBI-probes compared to conventional, larger tools

Secondary Outcome

None

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- University Medical Center **Hals-Nasen-Ohrenheilkunde, Kopf- und Halschirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/01**
- 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

Male and female patients and test persons over the age of 18 yrs.

Exclusion criteria

Persons under the age of 18 yrs., pregnant women, emergency patients, persons unable to consent, persons suffering from dementia, disabled persons

Addresses

- **Primary Sponsor**

**Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*



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**Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.uniklinik-freiburg.de**

■ **Contact for Scientific Queries**

**Universitätsklinikum Freiburg, Klinik für Hals-Nasen-Ohrenheilkunde, Kopf-
und Halschirurgie
Mr. Dr. med. Christoph Becker
Killianstraße 5
79106 Freiburg
Germany**

Telephone: **+4976127042010**

Fax: [---]*

E-mail: **christoph.becker at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Public Queries**

**Universitätsklinikum Freiburg, Klinik für Hals-Nasen-Ohrenheilkunde, Kopf-
und Halschirurgie
Mr. Dr. med. Christoph Becker
Killianstraße 5
79106 Freiburg
Germany**

Telephone: **+4976127042010**

Fax: [---]*

E-mail: **christoph.becker at uniklinik-freiburg.de**

URL: [---]*

■ **Collaborator, Other Address**

**Universität Freiburg, Institut für Mikrosystemtechnik, Gisela-und-Erwin-Sick-
Professur für Mikrooptik
Mr. Prof. Hans Zappe
Georges-Köhler-Allee 102
79110 Freiburg
Germany**

Telephone: **+49 761 2037560**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

Collaborator, Other Address

**Universität Freiburg, Institut für Mikrosystemtechnik, Gisela-und-Erwin-Sick-
Professur für Mikrooptik
Mr. Prof. Hans Zappe
Georges-Köhler-Allee 102
79110 Freiburg
Germany**

Telephone: **+49 761 2037560**

Fax: /

E-mail: **hans.zappe at imtek.uni-freiburg.de**

URL: **https://www.imtek.de/professuren/mikrooptik/startseite**

Sources of Monetary or Material Support

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

**Universitäts-HNO-Klinik Freiburg
Mr. Dr. med. Christoph Becker
Killianstr. 5
79106 Freiburg
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

■ Recruitment Status: **Recruiting planned**

■ 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.