Trial Description

Title

Sentinel lymph node excision in the head and neck area for cutaneous malignancies: clinical evaluation of a hybrid tracer (technetium and indocyanine) versus technetium labeling

Trial Acronym

SLNE-Hybrid

URL of the trial

[---]*

Brief Summary in Lay Language

**In this randomized study, a hybrid tracers of technetium and indocyanine green should be investigated. This hybrid tracer is the combination of two substances with the aid of detecting two different qualities: radioactive and fluorescence.
It will be examined in this two-arm study how useful this combination marker during surgery and sentinel node lymph vessels in malignant skin cancer in the head and neck can be. The allocation to the two arms of the study carried out at random.
The markings applied before surgery can be compared with the marks during the operation by using the indocyanine green staining. It should further be made a comparison of the duration of surgery, and a cost analysis.**

Brief Summary in Scientific Language

In this prospective randomized study we will investigate the influence of the type of labeling (99mTechnetium + Indocyanin green vs. 99mTechnetium) on the detection rate of sentinel lymph nodes in the head and neck region, the rate of false negative sentinel node, the operation time and hospital costs.

Organizational Data

- DRKS-ID: **DRKS00004622**
- Date of Registration in DRKS: **2013/01/22**
- 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.: **12-4972-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **C43 - Malignant melanoma of skin**
- ICD10: **C44 - Other malignant neoplasms of skin**

Interventions/Observational Groups

- Arm 1: **Lymphoscintigraphy with 99m-technetium and intraoperative fluorescence detection of indocyanin green**
- Arm 2: **Lymphoscintigraphy with 99m-technetium**

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: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Rate of SN positivity in the two arms, examined by histopathology after the operative procedure

Secondary Outcome

False negative rate in the two arms (Local relapse within 1 year after the sentinel lymph node excision);
Difference in morbidity in terms of complication rate (clinical examination within the postopertive phase). Duration of surgery (in minutes); Number of excised lymph nodes per patient (operative report); Surgery costs

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Dermatologie, Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/25**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Age >18 years. Patients with a malignant melanoma in the head and neck area (stage IB and II; AJCC 2009). Patients with a squamousus cell carcinom in the head and neck (tumor thickness >4mm). Patients with a Merkel cell carcinom in the head and neck area.

Exclusion criteria

Age < 18 years, Indocyanin green intolerance, iodine allergy.

Addresses

- **Primary Sponsor**

  Universitätsklinikum Essen,
  Klinik für Dermatologie und Venerologie
  Hufelandstrasse 55
  45122 Essen

Primary Sponsor

Universitätsklinikum Essen,
Klinik für Dermatologie und Venerologie
Hufelandstrasse 55
45122 Essen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uk-essen.de**

■ **Contact for Scientific Queries**

Klinik und Poliklinik für Dermatologie, Venerologie und Allergologie
Universitätsklinikum Essen
Mr. Dr. Joachim Klode
Hufelandstr. 55
45147 Essen
Germany

Telephone: **0201-723-1812**
Fax: **[---]***
E-mail: **joachim.klode at uk-essen.de**
URL: **www.uk-essen.de**

■ **Contact for Public Queries**

Klinik und Poliklinik für Dermatologie, Venerologie und Allergologie
Universitätsklinikum Essen
Mr. Dr. Ingo Stoffels
Hufelandstr. 55
45147 Essen
Germany

Telephone: **0201-723-3642**
Fax: **[---]***
E-mail: **ingo.stoffels at uk-essen.de**
URL: **www.uk-essen.de**

Sources of Monetary or Material Support

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

Universitätsklinikum Essen
Hufelandstraße 55
45147 Essen
Germany

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

Universitätsklinikum Essen
Hufelandstraße 55
45147 Essen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinikum-essen.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/12/31**

Trial Publications, Results and other documents

- Paper **Hybrid Tracer_ EJNMMI**

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