PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Randomised Phase II Screening Study to be Used in an TP/TPF-chemotherapy (Short Induction) Before TP/TPF-induction, Radiotherapy With or Without Cetuximab in the Primary Therapy of the Only by Laryngectomy Operable Carcinoma of the Larynx/Hypopharynx

Trial Acronym

DeLOS II

URL of the trial

[---]*

Brief Summary in Lay Language

The DeLOS II trial is a multicenter randomised phase II trial investigating a TP/5-Fluorouracil (TPF)-chemotherapy with or without cetuximab for Patients with only by laryngectomy operable carcinoma of the larynx/hypopharynx. Patients were divided in responder or non-responder after 4 weeks. Since August 2009 Responder receive TP with or without Cetuximab + radiation. (Until february 2009 Responder received TPF with or without Cetuximab + radiation.) Planned accrual is 85 patients per treatment arm. The primary study endpoint is a confirmatory proof of an adequate survival rate with a functionally larynx-conserving 2 years after randomisation.

Brief Summary in Scientific Language

[---]*

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

[---]*

Description IPD sharing plan

[---]*

[---]*

Organizational Data

- DRKS-ID: **DRKS00005561**
- Date of Registration in DRKS: **2014/09/01**
- Date of Registration in Partner Registry or other Primary Registry: **2007/07/27**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00508664 (ClinicalTrials.gov)**
- Sponsor-ID: **TP(F)+Radiation+/-Cetuximab (University of Leipzig)**

Health condition or Problem studied

- Free text: **Squamous Cell Carcinoma of the Hypopharynx**
- Free text: **Larynx Carcinoma**
- ICD10: **C13 - Malignant neoplasm of hypopharynx**
- ICD10: **C32 - Malignant neoplasm of larynx**

Interventions/Observational Groups

- Arm 1: **Radiation: Radiation**
- Arm 2: **Drug: Cetuximab**
- Arm 3: **Drug: Docetaxel**
- Arm 4: **Drug: Cisplatin (TP)**
- Arm 5: **Drug: 5-Fluorouracil (TPF) (only until Feb 2009)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Confirmatory proof of an adequate survival rate with a functionally larynx-conserving 2 years after randomisation; time frame: LFS-rate 2 years after randomisation

Secondary Outcome

- Descriptive analysis of the study arms concerning the secondary end criteria of the study; time frame: LSF 2 years after randomisation
- Explorative comparison of the study arms concerning the primary and secondary end criteria of the study; time frame: LSF 2 years after randomisation

Countries of recruitment

- AT **Austria**
- DE **Germany**

Locations of Recruitment

- **Medizinische Klinik I Prosper-Hospital, Recklinghausen**
- **Helios Klinikum Erfurt GmbH Klinik für HNO-Heilkunde, Plastische Operationen, Erfurt**
- **Universitätsklinik Aachen, Aachen**
- **Klinikum Neukölln, Vivantes GmbH, Berlin**
- **Charité, Campus Benjamin Franklin, Berlin**

- **Klinikum Bielefeld-Mitte, Bielefeld**
- **Malteser Krankenhaus St. Anna gGmbH, HNO-Klinik, Duisburg**
- **Klinikum Fulda gAG, Klinik für Hals-Nasen-Ohrenkrankheiten, Fulda**
- **Medizinische Hochschule Hannover, Hannover**
- **Klinikum Hannover Nordstadt, Hannover**
- **Universitätsklinikum Heidelberg, Heidelberg**
- **Universitätsklinikum Jena, Jena**
- **Westpfalz-Klinikum GmbH, Kaiserslautern**
- **St. Vincentius Kliniken, Karlsruhe**
- **Klinikum Kassel GmbH, Kassel**
- **Katholisches Klinikum Koblenz Marienhof, Koblenz**
- **Universitätsklinik Köln, Köln**
- **Universitätsklinikum Leipzig, Leipzig**
- **Universtitätsklinikum Schleswig-Holstein, Lübeck**
- **Klinikum Großhadern, München**
- **Medizinische Fakultät der Westfälischen Wilhelms-Universität Münster, Münster**
- **Südharz-Krankenhaus Nordhausen gGmbH, Nordhausen**
- **Klinikum Oldenburg gGmbH, Oldenburg**
- **Klinikum Ernst von Bergmann gGmbH, Potsdam**
- **Universtitätsklinikum Regensburg, Regensburg**
- **Klinikum Stuttgart Katharinenhospital, Klinik für HNO-Krankheiten, Stuttgart**
- **Bayerischen Julius Maximillians-Universtät Würzburg, Würzburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2007/07/31**
- Target Sample Size: **170**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

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Additional Inclusion Criteria

- Histologically confirmed, primary only with laryngectomy respectable squamous-cell carcinoma of the larynx or hypopharynx

- T3-T4a carcinoma of the glottis

- T2-T4a carcinoma of the supraglottic, only controllable by laryngectomy and if applicable by root of tongue segmental resection

- T2-T4a carcinoma of the hypopharynx only controllable by laryngectomy (for example T2, post cricoidal) and hypopharynx segmental resection

- N-status: cervical metastases (N0-N3) have to be rehabilitate by surgical procedures

- Blood count: Leukocytes >3500/mm\3, Neutrophils > 1500/ mm\3, Thrombocytes > 8000/ mm\3

- Clinical chemistry:

- adequate renal function, defined by serum creatinine and urea not higher than 25% upper NL, creatinine-clearance > 60 ml/min/1,72 m\2

- adequate hepatic function with SGOT, SGPT not higher than 50% and bilirubin not higher than upper NL

- electrolytes at NL

- anesthetic risk normal or low-grade elevated

- age 18-75 years

- written informed consent

- effective contraception after individual advice for men and women if there is a possibility of reproductive potential (effective contraception are: oral contraception with estrogen and gestagen (no minipill), vaginal ring, contraception patch, estrogen free ovulation suppressors, hormone spiral with progesterone, injection for three month with depot gestagen, hormone releasing

implantation (luteal hormone containing rod), abstinence or sterilization (vasectomy) of the male)

Exclusion criteria

- primary cancer treatable by operational larynx -conserving procedures

- distant metastases (M1-Status)

- total tumor volume exceeding 80 ml or larynx skeleton punctuated with infiltration of surrounding soft tissues respectively the esophageal aditus (exclusive cartilage infiltration represents no exclusion criteria)

- tumor-specific prior chemo or radiotherapy

- metachronous or synchronous malignant tumor (exception basalioma) [in case of a controlled tumor of different localization with a non-treated interval over 5 years to the present therapy the patient can be included after consultation with the coordinating investigator]

- life expectancy < 3 month

- Karnofsky performance status < 70%

- serious cardiopulmonary concomitant disease (cardiac insufficiency grade III and IV according NYHA status, myocardial infarction, angina pectoris, respiratory global insufficiency)

- Chronic diseases with permanent-therapy (uncontrolled diabetes, active rheumatoid arthritis)

- recurrent pneumonia, COPD GOLD stage <2, chronic inflammation of intestine or any other concomitant diseases, which disallow study participation in the opinion of the responsible physician

- Other circumstances (contra-indications), which disallow treatment with Docetaxel, Cisplatin, 5-FU, Cetuximab or radiotherapy

- Expected absent patient compliance

- Periodic follow-up not possible (for example address outside germany)

- Pregnant or breast-feeding woman

- Absent or constricted legal capacity

- Participation to another clinical trial with any investigational study within 30 days prior to study screening

Addresses

■ **Primary Sponsor**

University of Leipzig

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

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■ **Collaborator, Other Address**

Sanofi

Collaborator, Other Address

Sanofi

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Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

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

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2013/12/01
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.