

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Examination, validation and translation of signaling networks of cellular radiation response**

### Trial Acronym

**ZiSStrans**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**This research is conducted to establish if the occurrence of oral mucositis and xerostomia due to reduced salivation during therapy is caused by differences in the radiation sensitivity of mucosal cells and / or by differences in the composition of saliva (protein components).**

### Brief Summary in Scientific Language

**Tumor patients undergoing regular radiation therapy are examined for the manifestation of side effects (radiogenic mucositis and xerostomia), additional clinical parameters are collected from existing medical records, and samples of saliva, serum and full blood are collected and stored for marker examinations. In addition, before radiation therapy a single biopsy of oral mucosa is collected to investigate patient-specific cellular radiation sensitivity (colonisation, proliferation, migration).**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00012947**
- Date of Registration in DRKS: **2019/06/04**
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Date of Registration in DRKS: **2019/06/04**

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.: **413/17** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **C10 - Malignant neoplasm of oropharynx**
- ICD10: **C13 - Malignant neoplasm of hypopharynx**
- ICD10: **C32 - Malignant neoplasm of larynx**

## Interventions/Observational Groups

- Arm 1: **Collecting clinical patient data; Oral Mucositis Assessment; oral mucosa biopsy; samples of resting saliva and sample of serum before radiochemotherapy; preparation of biological materials: proteome analysis of saliva, cell culture of keratinocytes, in vitro testing of radiation sensitivity, microRNA analyses of serum samples**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
-

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Assignment: **Single (group)**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Prediction of individual, i.e. patient-specific side effects and tumor control during / after radiation therapy**

### Secondary Outcome

/

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- University Medical Center **Klinik für Strahlenheilkunde, Freiburg im Breisgau**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/09/01**
- Target Sample Size: **150**
- 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**

**Histologically confirmed carcinoma of the oral cavity, the oropharynx, hypopharynx or larynx; planned radiation therapy in the head-neck-area according to a standardized protocol (cisplatin-based radiochemotherapy, radiation dose 60-70 Gy, fractionation 5 x 2 Gy / week); written consent**

#### **Exclusion criteria**

**Complete removal of major salivary glands in the context of surgical tumor therapy**

#### **Addresses**

##### ■ **Primary Sponsor**

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##### ■ **Contact for Scientific Queries**

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##### ■ **Contact for Public Queries**

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### Contact for Public Queries

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### Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Fax: [---]\*

E-mail: [---]\*

URL: **www.bmbf.de**

### Status

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

### Trial Publications, Results and other documents

\* 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.