

Trial Description**Title**

Prospective study to determine the radiation-related effects on the cochlea and vestibular organ in intracranial and extracranial head and neck tumours

Trial Acronym

VESTIRAD

URL of the trial

[---]*

Brief Summary in Lay Language

Prospective recording of radiation-induced changes in inner ear and balance function in patients with intra- or extracranial head and neck tumours before, during and after irradiation of the temporal bone region. This is done on the basis of modern vestibular 5-sensor diagnostics (to measure all semicircular canals as well as the sacculus and utricle), subjective and objective hearing tests and on the basis of standardised and validated questionnaires.

Brief Summary in Scientific Language

The aim of the study is the prospective assessment of radiation-induced damage to the inner ear as well as the vestibular organ in patients with head and neck carcinomas and the recording of their effect on the subjective discomfort and quality of life of the affected patients. In particular, the aim is to determine the dose at which patients suffer from subjective and objective dizziness or hearing loss, which parts of the vestibular system (semicircular canals, otoliths) and which frequency range of the vestibulo-ocular reflex (VOR) and the hearing system are most affected. In addition, the influence of radiation on the development of tympanic effusion and conductive hearing loss and the extent to which the audiological and peripheral-vestibular functional deficits determined correlate with the subjective complaints of the patient will be investigated. The improved assessment of the postradiogenic consequential damages should serve in the future for improved monitoring, prognosis assessment and therapy and form the basic knowledge before possible periinterventional radiation prophylaxis.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021027**
- Date of Registration in DRKS: **2020/03/06**
- 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.: **64/19** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C32 - Malignant neoplasm of larynx**
- ICD10: **C11 - Malignant neoplasm of nasopharynx**
- ICD10: **C14 - Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx**
- ICD10: **C13 - Malignant neoplasm of hypopharynx**
- ICD10: **C10 - Malignant neoplasm of oropharynx**
- ICD10: **C12 - Malignant neoplasm of piriform sinus**
- ICD10: **C07 - Malignant neoplasm of parotid gland**
- ICD10: **C08 - Malignant neoplasm of other and unspecified major salivary glands**
- ICD10: **C09 - Malignant neoplasm of tonsil**
- ICD10: **C00 - Malignant neoplasm of lip**
- ICD10: **C01 - Malignant neoplasm of base of tongue**
- ICD10: **C02 - Malignant neoplasm of other and unspecified parts of tongue**
- ICD10: **C03 - Malignant neoplasm of gum**
- ICD10: **C04 - Malignant neoplasm of floor of mouth**
- ICD10: **C05 - Malignant neoplasm of palate**
- ICD10: **C06 - Malignant neoplasm of other and unspecified parts of mouth**
- ICD10: **C30 - Malignant neoplasm of nasal cavity and middle ear**
- ICD10: **C31 - Malignant neoplasm of accessory sinuses**
- ICD10: **D33 - Benign neoplasm of brain and other parts of central nervous system**
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ICD10: **C76.0 - Malignant neoplasm of other and ill-defined sites: Head, face and neck**

Interventions/Observational Groups

- Arm 1: **Patients with head and neck cancer who will receive radiotherapy**
- Arm 2: **Patients with head and neck cancer who receive additional chemotherapy.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

pre- and post-therapeutic hearing threshold, tympanic membrane compliance and vestibular function parameters and - subjective dizziness (DHI-G) and quality of life (EORTC-QLQ-C30)

Secondary Outcome

Comparison of the above-mentioned parameters between the patient group with combined cisplatin-containing radiochemotherapy and the patient group with radiation alone

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **HNO Uniklinik Freiburg , Freiburg im Breisgau**



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/04/08**
- 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

Inclusion criterion for the study is the indication of primary or adjuvant irradiation in patients with histologically proven malignancy in the head and neck region. Only patients who have reached the age of 18 at the time of study enrolment, have a written and spoken command of the German language and are able to participate in regular tumor follow-ups will be included. Patients with planned combined cisplatin-containing radiochemotherapy will be included as a separate study arm and later compared to patients with radiotherapy alone.

Exclusion criteria

Excluded are all patients with tumor-related affection of the vestibular organ, the inner ear or the brain stem which could influence the vestibular diagnostics, patients who are pre-irradiated in the head and neck area as well as patients with known peripheral-vestibular disorders. These include patients with a history of vestibular neuropathy within the last 6 months as well as patients with a history of vestibular paroxysm, endolymph hydrops (M.Menière) or vestibular schwannoma.

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

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

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URL: [---]*

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.