Trial Description

Title

Simultaneous Integrated Protection of Challenging Indications of SBRT

Trial Acronym

SIP CHAI

URL of the trial

[---]*

Brief Summary in Lay Language

Due to the close proximity of the organs, mostly the stomach, the duodenum or the bronchial tree, with the tumor, during stereotactic radiotherapy, a dose reduction is sometimes necessary in order to reduce the risk of toxicities. This might lead to a tumor relapse. In order to avoid a dose reduction to the whole tumor, we defined an extra region which consists of the overlapping parts the organs with the tumor, which receives a lower dose.

Brief Summary in Scientific Language

The close proximity of organs at risk (OAR), mostly the stomach, the duodenum or the bronchial tree, with the tumor in stereotactic radiotherapy, a dose reduction is required in the entire Planning Target Volume (PTV) during SBRT in order to comply with dose constraints. But a reduction of the dose in the entire PTV hampers local control. In order to avoid a general dose reduction in the PTV, we defined a simultaneous integrated protection volume (SIP) which consists of the overlapping parts the PTV with the PRV (Planning Risk Volume) of an OAR. The dose within the SIP should be as high as possible but still within the constraints for the OARs. In this study we will evaluate the concept of simultaneous integrated protection volume (SIP) regarding toxicity.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015816**
- Date of Registration in DRKS: **2019/11/13**

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Date of Registration in DRKS: **2019/11/13**

- 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.: **185/19 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C33 - Malignant neoplasm of trachea**
- ICD10: **C34 - Malignant neoplasm of bronchus and lung**
- ICD10: **C22 - Malignant neoplasm of liver and intrahepatic bile ducts**
- ICD10: **C25 - Malignant neoplasm of pancreas**
- ICD10: **C74 - Malignant neoplasm of adrenal gland**
- ICD10: **C77 - Secondary and unspecified malignant neoplasm of lymph nodes**
- ICD10: **C76 - Malignant neoplasm of other and ill-defined sites**
- ICD10: **C79 - Secondary malignant neoplasm of other and unspecified sites**

Interventions/Observational Groups

- Arm 1: **SBRT using a Simultaneous Integrated Protection (SIP)-IMRT technique allowing commonly employed doses to the dominant PTV (PTVdom) either as 5 fractions x 10 Gy or as 8 fractions x 7.5 Gy or as 12 fractions x 5.5 Gy, and reduced doses to the PTVsip, which consists of the overlap between the PTV and the planning risk volume (PRV) of the organ at risk (OAR). The PTVdom is the PTV minus the PTVsip.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
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Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Acute (up to 90 days) and late toxicity (project duration: 24 months)

Secondary Outcome

Response rate (RECIST, PERCIST), Local control rates, Progression-free survival, Overall Survival

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Strahlenheilkunde, Freiburg im Breisgau**
- University Medical Center **Universitätsklinik für Strahlentherapie, Magdeburg**
- Medical Center **Kliniken Maria Hilf , Mönchengladbach**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/12/01**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Before registration, patient's written informed consent has been obtained;
2. Age ≥ 18 years, male and female patients;
3. Legal capacity, patient is able to understand the nature, significance, and consequences of the study;
4. Diagnosis of cancer, confirmed by either histology, cytology, or clinically (imaging and tumour markers);
5. Tumour located close to highly vulnerable organs at risk (OAR): (1) precluding SBRT at doses to a biologically equivalent dose (BED) of <80 Gy (αβ10) prescribed to the Planning target volume (PTV)according to ICRU with standard planning; (2) due to violation of dose constraints for OAR as specified in Table 2 (see Appendices);
6. Tumour location between the plane of the cranial tips of the lungs and the inferior border of the pelvis. All lesions need to be treatable by local curative therapy;
7. 1-3 lesions with at least 1 lesion requiring SIP-IMRT; all diagnosed lesions are treated with a local treatment method; combinations of SBRT and surgery or other local therapies are allowed;
8. WHO performance status ≤ 2;
9. Life expectance ≥ 6 months;
10. Patients of childbearing / reproductive potential should use adequate birth control measures, during the study treatment period. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly;
11. For metachronous lesions patients cannot be registered in this study more than once.

Exclusion criteria

1. Prior radiotherapy to the region(s) to be treated;
2. Chemotherapy and/or targeted treatment within 2 weeks before the start of SBRT;
3. Presence of infiltration of OARs such as tracheal, oesophageal infiltration or infiltration of small/large bowel or stomach;
4. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the study.

Addresses

- **Primary Sponsor**

  Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde
  Ms. Prof. Dr. med. Anca-L. Grosu
  Robert-Koch-Str. 3

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Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde
Ms. Prof. Dr. med. Anca-L. Grosu
Robert-Koch-Str. 3
79106 Freiburg
Germany

Telephone: **0761 270 94610**
Fax: **[---]***
E-mail: **anca.grosu at uniklinik-freiburg.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde
Ms. Dr. med. Eleni Gkika
Robert-Koch-Str. 3
79106 Freiburg
Germany

Telephone: **0761 270 95200**
Fax: **[---]***
E-mail: **eleni.gkika at uniklinik-freiburg.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde
Ms. Dr. med. Eleni Gkika
Robert-Koch-Str. 3
79106 Freiburg
Germany

Telephone: **0761 270 95200**
Fax: **[---]***
E-mail: **eleni.gkika at uniklinik-freiburg.de**
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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting planned**
- 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.*