



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

## Trial Description

### Title

**Biomarker associated with the radiation therapy of renal cell cancer.**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

[---]\*

### Brief Summary in Scientific Language

**This explorative study examines whether the response of renal cell cancer to stereotactic radiotherapy (SBRT) in 10 patients with von Hippel-Lindau syndrome correlates with modifications in gene expression in peripheral blood and urine. These data can be used to draw conclusions regarding the underlying mechanisms of SBRT (e.g. apoptosis, inflammation, immune response) to optimize dose, application mode and synergistic adjuvant therapies.**

## Organizational Data

- DRKS-ID: **DRKS00010924**
- Date of Registration in DRKS: **2016/09/23**
- 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.: **266/15** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs



## Health condition or Problem studied

- ICD10: **C64 - Malignant neoplasm of kidney, except renal pelvis**

## Interventions/Observational Groups

- Arm 1: **During the course of radiation therapy, expression profiles and proteomic analyses from blood and urine will be used to elucidate the processes induced by radiation.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Modifications of biomarker (urine, blood) in 10 patients**

### Secondary Outcome

n/a

## 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: **2016/01/15**
- Target Sample Size: **10**
- 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

**VHL patients with RCC and SBRT**

## Exclusion criteria

**Patients with Hb < 10 g/dL, and patients unable to collect substantial quantities of urine (≥ 250 ml)**

## Addresses

### ■ Primary Sponsor

**Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde  
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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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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

DRKS-ID: **DRKS00010924**

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**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

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*\* 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.*