



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

## Trial Description

### Title

**Stereotactic fraktionated radiotherapy in patients with medically inoperable small lung tumors (STRIPE I): a phase II study**

### Trial Acronym

**STRIPE I**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**stereotactic fractionated radiotherapy in patients with not more than 2 small lung tumors (NSCLC or metastases of other primaries), who are medically inoperable by interdisciplinary consensus**

### Brief Summary in Scientific Language

**phase II study to evaluate the local control after stereotactic fractionated radiotherapy in patients with medically inoperable small lung tumors**

## Organizational Data

- DRKS-ID: **DRKS00003658**
- Date of Registration in DRKS: **2012/04/18**
- 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.: **366/08** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **C34 - Malignant neoplasm of bronchus and lung**
- ICD10: **C78.0 - Secondary malignant neoplasm of lung**

## Interventions/Observational Groups

- Arm 1: **stereotactic fractionated radiotherapy of small lung tumors in 3 to 5 fractions**

## Characteristics

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

## Primary Outcome

**local tumor control after two years of follow-up**

## Secondary Outcome

- **actuarial local progression free survival**
- **overall survival over two years of follow-up**
- **standardized QoL (EORTC QLQ C30 and LC13)**
- **individual QoL (SEIQoL-DW Score)**
- **Toxicity of SR in small lung tumors (CTC score)**
- **Feasibility of integrated cone beam CT for patient positioning in SR**
- **Impact of respiratory gated FDG-PET/CT in SR planning and follow up**
- **Detection of tumor progression by CT vs. FDG-PET**

## 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: **2011/02/15**
- Target Sample Size: **100**
- 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

- **presence of one or two FDG-PET positive pulmonary nodules  $\leq$  5cm diameter suspicious for primary lung cancer or metastasis by CT**
- **Karnofsky index  $\geq$  60%**
- **Life expectancy > 6 months**
- **Age > 18 years (no other age limits)**
- **Informed consent signed in accordance with institutional protocol**

## Exclusion criteria

- **NSCLC: FDG-PET N+ if not ruled out by mediastinoscopy or other tissue sampling**
- **in metastases: disseminated progressive disease without local control to be reasonably expected by current treatment**
- **Histologically proven SCLC**
- **More than two lesions to treat**
- **Diameter of tumor > 5cm**
- **Systemic therapy +/- one week of treatment**
- **psychological/mental status does not allow informed consent and participation in QoL assessments**
- **Pregnancy**

## Addresses

- **Primary Sponsor**

**Universitätsklinikum Freiburg, Klinik für Strahlenheilkunde  
Robert-Koch-Str. 3  
79106 Freiburg  
Germany**



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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**

### ■ **Private sponsorship (foundations, study societies, etc.)**

**Deutsche Krebshilfe e.V.  
Buschstr. 32  
53113 Bonn  
Germany**

Telephone: [---]\*

Fax: [---]\*

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E-mail: [---]\*

URL: [---]\*

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/11/26**

## Trial Publications, Results and other documents

*Please note:*

*There are additional attributes available concerning this trial. To open an extended view please [click here](#).*