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

Trial Description

Title

L-AP-IS: Lung cancer, Ablative high Precision radiotherapy and the Immune System: Evaluation of the immune-modulatory effects of stereotactic body radiation therapy (SBRT) of pulmonary lesions

Trial Acronym

L-AP-IS

URL of the trial

[---]*

Brief Summary in Lay Language

High precision radiotherapy (SBRT) leads to cell death of tumor cells, but also to specific immune response against the tumor. Main objective of this trial is to analyse potential changes of certain biomarkers of the immune response in the blood of patients who get tretaed with SBRT for lung cancer or lung metastases.

Brief Summary in Scientific Language

The main objective of this approach is to prospectively evaluate novel and minimally invasive biomarkers of (tumor specific) immune response to SBRT in NSCLC patients, as well as in patients with solitary or oligometastatic pulmonary metastases.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011266**
- Date of Registration in DRKS: **2017/01/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00011266**
Date of Registration in DRKS: **2017/01/10**
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.: **38/16 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C34 - Malignant neoplasm of bronchus and lung**

Interventions/Observational Groups

- Arm 1: **Blood samples of patients with primary or recurrent NSCLC collected before, during and after SBRT (Stereotactic Body RadioTherapy) will be evaluated for immunespecific, circulating biomarkers.**
- Arm 2: **Blood samples of patients with pulmonary metastases will be evaluated for immune-specific, circulating biomarkers.**
- Arm 3: **Patients with systemic treatment within 3 months before SBRT will be separately analyzed and compared to the patients who received no systemic treatment.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Other**
- Phase: **I**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Other**

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

Who is blinded: **[---]***

Control: **Other**

Purpose: **Basic research/physiological study**

Assignment: **Other**

Phase: **I**

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

Primary Outcome

Increase of CTL counts six weeks after SBRT compared to baseline

Secondary Outcome

- Significant changes in number and phenotype of lymphocytes
- Significant changes in number and phenotype of myeloid cells
- Significant changes in circulating biomarkers of immune response in the plasma
- Association between treatment related data and changes in different biomarkers of immune response
- Association between treatment outcomes and changes in different biomarkers of immune response
- Differences in the above mentioned endpoints between patients with or without prior / simultaneous radiation and /or systemic therapy

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: **2016/09/06**
- Target Sample Size: **75**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2016/09/06**

Target Sample Size: **75**

- 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

• Primary or recurrent non-metastatic NSCLC or
• Solitary or oligometastasic pulmonary metastasis of otherwise controlled malignant
• Lesions confirmed by either histology or cytology or clear imaging signs of malignant tumors
• Patient scheduled and eligible for SBRT with curative intention
• Whole body FDG-PET scan + WB-CT or CT of chest and upper abdomen
• Written informed consent must be given according to ICH/GCP, and national/local regulations
• Adequate birth control measures during the study treatment period

Exclusion criteria

• Other active or significantly bone marrow suppressing malignancy
• WHO performance status < 2
• Prior radiotherapy to chest and/or mediastinum within 3 months before the start of SBRT
• Chemotherapy and/or targeted treatment within 3 months before the start of SBRT
• Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
• Pregnancy

Addresses

- **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
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.*