Trial Description

Title

Evaluation of Systemic Effects of Combined Palliative Radiation Therapy and Immunotherapy in Patients with Metastatic Non-Small Cell Lung Cancer after Insufficient Response to Immune Checkpoint Blockade

Trial Acronym

RadImmun-NSCLC

URL of the trial

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Brief Summary in Lay Language

There is data showing that radiation therapy may not only kill tumor cells, but also stimulate the body's immune system, so that it can "attack" the tumor. This reaction could be enhanced by the combination with the so-called immune therapy (such as Nivolumab). In this study we aim to evaluate the tumor response after such a combination therapy and to pay special attention to the tumor sites which were not irradiated.

Brief Summary in Scientific Language

Radiation therapy appears to trigger a local and even systemic immune response through immunogenic tumor cell death. The combination between radiation- and immunotherapy may further lead to better tumor control. Our primary objective is to investigate the clinical efficacy of combining immunotherapy and radiotherapy and to describe possible abscopal effects.
An amendement to the first protocol was approved by the Ethik-Comission of the Albert-Ludwigs-Universität Freiburg on the 30th October 2018 (ID 297/17). Within this Amendment we expanded the protocol to comprise all approved checkpoint-inhibitors and changed the title of the trial.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00013531**
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Date of Registration in DRKS: **2017/12/04**

- 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.: **297/17 , 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: **Radiation therapy, immunotherapy with approved checkpoint inhibitors, tumor assessment by imaging, collection of blood samples (and biopsy material), evaluation of results**

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: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Overall Response Rate (ORR) according to RECIST 1.1 and irRC; Best response of non-target index-lesions and thus evaluation of systemic immune-related effects (abscopal effects)

Secondary Outcome

Progression-free survival; Acute and late toxicity induced by the combined therapy; Local control achieved by radiation therapy; Overall survival; Quality of life as measured by means of EORTC QLQ-C30 questionnaire

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: **2018/03/22**
- 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

Patients with metastatic NSCLC and progressive disease; At least three lesions measurable by computed tomography scan or magnetic resonance imaging; Patients presenting the indication for radiation therapy, with a minimum of 2 metastases not amenable to radiation therapy; Mixed or partial response under immunotherapy with checkpoint inhibitors; Minimum life expectancy of 3 months; Adequate bone marrow function; Adequate liver function; Written informed consent must be obtained according to ICH/GCP, and national/local regulations; Adequate birth control measures during the study treatment period.

Exclusion criteria

Age < 18 years; Central nervous system metastases mandating active treatment; ECOG performance status > 2; Female subjects who are pregnant; Patients under chronic treatment with systemic immunosuppressive drugs for a period of at least 4 weeks and whose treatment was not stopped 1 week prior starting the study treatment; Patients with active, known, or suspected autoimmune disease; Other active or significantly bone marrow-suppressing malignancy or therapy; Known activating EGFR Mutation or a known ALK Translocation; Patients with previous malignancies; Psychological, familial, sociological or geographical factors potentially hampering compliance with the study protocol and follow-up.

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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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.*