PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Targeted Natural Killer (NK) Cell Based Adoptive Immunotherapy for the Treatment of Patients With Non-Small Cell Lung Cancer (NSCLC) After Radiochemotherapy (RCT)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Targeted Natural Killer (NK) cell based adoptive immunotherapy for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) after radiochemotherapy (RCT)

Brief Summary in Scientific Language

Patients with non-small cell lung carcinoma (NSCLC) in stage III A and III B showing at least stable disease after RCTx will be enrolled into the clinical trial. The aim of the study is to show the efficacy of an adjuvant treatment with Hsp70-peptide TKD/IL-2 activated, autologous NK cells following completion of standard radiochemotherapy (Cisplatin/Vinorelbine). Patients will be randomized 1:1 either to the interventional study group to receive 4 cycles of autologous immunotherapy with activated NK cells or to the control group (BSC).

Organizational Data

- DRKS-ID: **DRKS00010746**
- Date of Registration in DRKS: **2016/06/29**
- Date of Registration in Partner Registry or other Primary Registry: **2014/02/25**

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2008-002130-30**
- Primary Registry-ID: **NCT02118415 (ClinicalTrials.gov)**
- Sponsor-ID: **NSCLC-TKD/IL-2 (Technische Universität München)**
- Other Secondary-ID: **2008-002130-30**

Health condition or Problem studied

- Free text: **NSCLC Stage IIIA/B**
- ICD10: **C34 - Malignant neoplasm of bronchus and lung**

Interventions/Observational Groups

- Arm 1: **Other: Hsp70-peptide TKD/IL-2 activated, autologous NK cells**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

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

Control: **Control group receives no treatment**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **II**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Progress free survival; time frame: follow up after randomization for at least 18 months

Secondary Outcome

- overall survival (OS); time frame: follow up after randomization for at least 18 months
- toxicity (AE and SAE); time frame: follow up after randomization for at least 18 months
- quality of life (QoLQ-30, LC-13); time frame: follow up after randomization for at least 18 months
- biological parameters (NK cell activation); time frame: follow up after randomization for at least 18 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Klinikum rechts der Isar, Strahlentherapie und Radiologische Onkologie, Munich**

Recruitment

- Planned/Actual: **[---]***

Planned/Actual: **[---]***

- (Anticipated or Actual) Date of First Enrollment: **2014/03/31**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- First diagnosis of histologically and/or cytologically proven and unresectable NSCLC with clinically stage III A and III B

- Completion of radiochemotherapy no longer than 8 weeks ago

- Progression free according to RECIST criteria at the first assessment after completion of RCTx

- Confirmed presence of Hsp70 on patient´s tumors

- ECOG Status(Appendices) ≤ 2

Exclusion criteria

- Any severe heart disease or any severe concomitant disease (ECOG stage > 2)

- NSCLC patients (stage IIIA/B) eligible for initial surgery with a confirmed consent of an interdisciplinary tumorboard

- Patients that show ALK positivity or an activating mutation of the EGFR-TK domain

- Patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology

- Receipt of immunosuppressive drugs including high dose systemic corticosteroids within 3 weeks before study entry. Low dose corticosteroids as they are a common treatment option for patients suffering from COPD are not an exclusion criterium

Addresses

- **Primary Sponsor**

  Technische Universität München

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

- **Contact for Scientific Queries**

  Klinikum rechts der Isar, TU München
  Michael Molls, Prof.

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

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  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 2

- Last processed date by ClinicalTrials.gov: 2016/06/22

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.