Trial Description

Title

Prospective evaluation of detection of circulating tumor DNA (ctDNA) to predict recurrence after definitive therapy of localized stage lung cancer (PREDICT)

Trial Acronym

PREDICT

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

Lung cancer patients treated with curative intent with suffer a recurrence in 30 – 80% of cases depending on stage and treatment. At recurrence, curative treatment is generally not possible. Therefore, patients are offered adjuvant therapy aimed at reducing the risk of recurrence. Adjuvant therapy consists of chemotherapy or more recently immuno-oncological treatment. With current diagnostic methods, the individual risk of recurrence cannot be estimated in detail. Therefore, all patients receive adjuvant treatment, even if they might be already cured by the definitive therapy and would not have a recurrence anyway. If these patients, who will not have a recurrence, could be identified prior to adjuvant therapy with a sufficiently accurate diagnostic test, these patients would not require adjuvant therapy. This would reduce morbidity, mortality, and cost. High-sensitivity measurement of pre- and post-therapeutic circulating tumor-DNA (ctDNA) in peripheral blood could provide such a test.
The planned PREDICT study will prospectively non-interventionelly test, whether the measurement of ctDNA is feasible in routine clinical practice, and whether ctDNA accurately predicts the risk of recurrence and survival in a lung cancer population treated with curative intent.

Organizational Data

- DRKS-ID: **DRKS00016416**
- Date of Registration in DRKS: **2019/04/08**
- 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.: **F-2019-002 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- Free text: **lung cancer nsclc and sclc**

Interventions/Observational Groups

- Arm 1: **Based on the ctDNA results, the study population will be analyzed in 3 arms:**

  1.ctDNA pre-therapeutically detectable and post-therapeutically not
- Arm 2: **2. ctDNA pre-therapeutically detectable und post-therapeutically detectable**
- Arm 3: **3. ctDNA pre-therapeutically not detectable**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, data analyst**
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Recurence-free survival at 1, 2, 3, 5 years post-therapeutically.

Secondary Outcome

Overall-survival

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik für Kardiologie und Pneumologie, Klinikum Esslingen, Esslingen am Neckar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/03/19**
- Target Sample Size: **180**
- 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 NSCLC stage I-IVA with planned curative therapy. SCLC stage I-IIIC with planned curative therapy.

Exclusion criteria

None

Addresses

- **Primary Sponsor**

  Klinik für Kardiologie und Pneumologie, Klinikum Esslingen
  73730 Esslingen
  Germany

Primary Sponsor

Klinik für Kardiologie und Pneumologie, Klinikum Esslingen
73730 Esslingen
Germany

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

■ **Contact for Scientific Queries**

Klinik für Kardiologie und PneumologieKlinikum Esslingen
Mr. Dr. med. Martin Faehling
Hirschlandstr. 97
73730 Esslingen
Germany

Telephone: **0711310382411**
Fax: **[---]***
E-mail: **m.faehling at klinikum-esslingen.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik für Kardiologie und PneumologieKlinikum Esslingen
Mr. Dr. med. Martin Faehling
Hirschlandstr. 97
73730 Esslingen
Germany

Telephone: **071131032402**
Fax: **[---]***
E-mail: **m.faehling at klinikum-esslingen.de**
URL: **[---]***

■ **Collaborator, Other Address**

Institut für Pathologie, Uniklinik Heidelberg
Mr. Prof. Dr. med. Albrecht Stenzinger
Germany

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

Sources of Monetary or Material Support

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

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

Klinik für Kardiologie und Pneumologie, Klinikum Esslingen
73730 Esslingen
Germany

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

Status

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

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Prüfplan**
- trial protocol (mandatory for transfer to Studybox) **Ablaufplan**

** 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.*