

Trial Description

Title

Validation of miRNA signatures for the early detection of lung cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the study is to measure markers in blood for the early detection of lung cancer. Therefore, a single blood sample is taken from a cohort of patients with suspicious X-ray or CT. This will help us to develop a blood-based test that could lead to earlier detection of lung cancer in the future and may improve survival and cure rate.

Brief Summary in Scientific Language

The aim of the study is to evaluate a novel miRNA-based methodology for the early detection of lung cancer (NSCLC) via a blood sample in a cohort of patients with suspicious X-ray or CT. The sensitivity and specificity of the marker set for the detection of lung cancer will be ascertained.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013647**
- Date of Registration in DRKS: **2018/02/05**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **159/2017** , **Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1208-7228**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Blood draw from patients with suspected lung tumor**
- Arm 2: **Blood draw from patients undergoing bronchoscopic evaluation of suspected non-malignant pulmonary diseases.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Validation of a previously identified signature of blood-based miRNA biomarkers for the identification of lung tumors. After measuring miRNA expression levels, it will be tested whether the signature can be used to discriminate between the two cohorts and if the results are comparable to previous tests.

Secondary Outcome

Testing the potential of a previously identified signature of blood-based miRNA biomarkers for lung cancer screening.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Lungenzentrum, Konstanz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/02/12**
- Target Sample Size: **303**
- 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

- 1. Male or female with presumable pathological findings through X-ray/CT**
- 2. Signed informed consent**
- 3. Patient is at least 18 years old**

Exclusion criteria

- 1. History of other primary malignancies**
- 2. Medication that influences the immune system (e.g. immunosuppressive drugs)**
- 3. Patient is younger than 18 years**

Addresses

- **Primary Sponsor**

**Hummingbird Diagnostics GmbH
Im Neuenheimer Feld 583**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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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.*