

## Trial Description

### Title

**Pulmonal lymph node micrometastasis in N0 patients with colorectal carcinoma after pulmonary metastasectomy**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**This is a retrospective, open, monocentric, in vitro study. The aim of the study is to detect micrometastases in pulmonary and mediastinal lymph nodes by means of molecular detection after metastasectomy, which have been diagnosed without tumor in the simple sectional diagnosis.**

### Brief Summary in Scientific Language

**Colorectal carcinoma is a malignant tumor of the intestine or rectum. It is the second most common malignancy of the woman and the third most common malignancy of the male, whereby it is the second most common cause of death in Germany.**

**Tumor growth has already taken place in up to 25% of the cases of diagnoses, while liver and lung are the most frequently affected organs. The lymph nodes in the lung are not radically removed during metastasectomy. The examination of the lymph nodes taken is performed by H.E. Coloring. Studies using immunohistochemical and / or genetic methods, the lymph nodes taken during primary tumor surgery, have shown that micrometastases occur in lymph nodes and have a negative effect on the survival rate and relapse rate. There is currently no investigation of pulmonary / mediastinal lymph nodes in metastatic colorectal carcinoma. A higher recurrence rate and / or poorer survival rate was described in studies which produced positive lymph node detection in pulmonary metastasectomy by means of only intersection diagnosis and H.E. staining. Therefore, the aim is to detect micrometastases in pulmonary and mediastinal lymph nodes by means of molecular detection after metastasectomy, which have been diagnosed without tumor in the simple sectional diagnosis. This study, which can show a link between micrometastases in lymph nodes after pulmonary metastasectomy and reduced survival rate and / or increased recurrence rate, can lead to better therapy, in the sense of extended oncological aftertreatment, modification of the surgical technique or also avoidance of over-therapy.**

## Organizational Data

- DRKS-ID: **DRKS00012512**
- Date of Registration in DRKS: **2017/10/09**
- 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.: **316/17 , 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: • **Retrospective opacity of patients undergoing surgical resection of pulmonary metastases with lymph node removal in colorectal carcinomas.**
  - **Creation of a database with clinical and pathological parameters.**
  - **Contact the Institute of Pathology Freiburg for the testing of tissue samples**
  - **Establish detection of micrometastases via CK 20 by RT-PCR / RT-qPCR**
  - **Statistical evaluation of the collected data.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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): **N/A**

## Primary Outcome

**detection of micrometastases**

## detection of micrometastases

### Secondary Outcome

**overall survival, recurrence rates and disease-free interval**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Klinik für Throaxchirurgie, Freiburg im Breisgau**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/09/22**
- Target Sample Size: **100**
- 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 colorectal cancer and curative resection of pulmonary metastases with lymph node resection at controlled primary tumor**

**- >18 years old**

**- patients of Thoracic Surgery during 2008 and 2017**

### Exclusion criteria

**Metastasis resection without lymph node removal**

## Metastasis resection without lymph node removal

### 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.