



Trial Description

Title

Molecular Pathology of Benign and Malignant Thyroid Tumors

Trial Acronym

Thyroid Molecular Pathology

URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

The retrospective and prospective basic research study is carried out with excess tissues at disposal after surgery of patients with thyroid tumors/tissues and their lymph node and distant metastases. Indications comprise oncology, general endocrinology as well as metabolic disorders such as diabetes type 2, metabolic syndrome and obesity. Clinical data will be correlated with results of molecular pathology analyses. Experimental methods planned comprise molecular genetics, proteomics, immunohistochemistry, and potentially generation of primary tissue cultures and murine xenografts.

Organizational Data

- DRKS-ID: **DRKS00010141**
- Date of Registration in DRKS: **2016/03/15**
- 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.: **Substudie zu 837.120.15 (9888) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **C73 - Malignant neoplasm of thyroid gland**
- ICD10: **D35 - Benign neoplasm of other and unspecified endocrine glands**

Interventions/Observational Groups

- Arm 1: **Retrospective and prospective basic research study on excess tissues at disposal after surgery of patients with thyroid tumors/tissues and their lymph node and distant metastases; molecular pathology analyses (molecular genetics, proteomics, immunohistochemistry, and potentially generation of primary tissue cultures and murine xenografts).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Identification of disease-associated genes as well as expression of genes and proteins

Secondary Outcome

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Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Mainz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/29**
- Target Sample Size: **800**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients who underwent surgery for benign and malignant thyroid tumors (or C-cell hyperplasia)

Exclusion criteria

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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): [---]*

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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.*