

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Assessment of breast lesion size and characterization: correlation of cone-beam breast-CT, digital breast tomosynthesis, full-field digital mammography with histopathological examination of mastectomy specimens

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

To assess breast lesions on mastectomy specimens with different imaging techniques, including mammography, tomosynthesis and breast computed-tomography compared to pathological analyses, in order to determine which imaging technique is the best for size assessment and lesion characterisation.

Brief Summary in Scientific Language

To compare the accuracy of breast lesion size measurement of cone-beam breast-CT (CBBCT), digital breast tomosynthesis (DBT) and full-field digital mammography (FFDM) with histopathological gold standard on mastectomy specimens.

Organizational Data

- DRKS-ID: **DRKS00012625**
- Date of Registration in DRKS: **2017/07/06**
- 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.: **2/12/14 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs



Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**

Interventions/Observational Groups

- Arm 1: **Imaging of mastectomy specimens by full-field digital mammography (FFDM), digital breast tomosynthesis (DBT) and cone-beam breast-CT (CBBCT) and histopathological assessment of breast lesions.**

Characteristics

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

Primary Outcome

Measurement (in millimeter) of breast lesions by FFDM, DBT and CBBCT immediately after mastectomy via a radiologist. Lesion size was measured in coronary orientation. Immediate histological fixation of the mastectomy specimen, histopathological size measurement of breast lesions (in millimeter) within a few days via a pathologist.

Secondary Outcome

Characterisation of breast lesions with the aforementioned imaging modalities in comparison to histopathology.

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- Medical Center **Göttingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/01**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients scheduled for mastectomy due to at least one biopsy-proven malignant breast lesion.

Exclusion criteria

Age under 18 years and prophylactic mastectomy.

Addresses

- **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.