Trial Description

Title

Surgical management of the axilla in primary systemic treatment of breast cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

primary endpoint:
concordance of primary minimal-invasive histologically proven suspicious axillary, clipmarked lymphnodes and sentinel lymphnodes after primary systemic treatment
secondary endpoint:
-creation of an oncologically safe concept to reduce axillary surgical radicalness after primary sytemic treatment in breast cancer patients with suspicious ipsilateral lymphnodes
-rate of detection of axillary sentinel nodes after primary systemic treatment
-predicitve value of the clipmarked lymphnode for metastatic disease in further lymphnodes after primary systemic treatment
-adverse events caused by clipmarking lymphnodes

After infromed consent the suspicious axillary lymphnode will be marked by a clip (HYDROMARK). The surgical procedure after primary systemic treatment depends on axillary response:
-iN+/pN0 before chemotherapy --> axillary SLNB and exstirpation of clipped lymph node, fresh frozen section, in case of metastatic lymph node complete axillary lymph node dissection
-pN+ before chemotherapy -->yiN0 --> axillary SLNB and exstirpation of clipped lymph node, fresh frozen section, in case of metastatic lymph node complete axillary lymph node dissection
-pN+ before chemotherapy --> yiN+ --> exstirpation of clipped lymph node and complete axillary lymph node dissection

Organizational Data

- DRKS-ID: **DRKS00009793**
- Date of Registration in DRKS: **2015/12/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

DRKS-ID: **DRKS00009793**
Date of Registration in DRKS: **2015/12/18**
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.: **A 2015-0160 , Ethik-Kommission an der Medizinischen Fakultät der Universität Rostock**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Before starting primary chemotherapy suspicious axillary lymphnodes will be marked by a clip (HYDROMARK)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- 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

concordance of primary minimal-invasive histologically proven suspicious axillary,

clipmarked lymphnodes and sentinel lymphnodes after primary systemic treatment
work measurement: surgery

Secondary Outcome

-creation of an oncologically safe concept to reduce axillary surgical radicalness after primary sytemic treatment in breast cancer patients with suspicious ipsilateral lymphnodes
-rate of detection of axillary sentinel nodes after primary systemic treatment
-predicitve value of the clipmarked lymphnode for metastatic disease in further lymphnodes after primary systemic treatment
-adverse events caused by clipmarking lymphnodes

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätfrauenklinik, Rostock**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/04**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

all patients diagnosed with invasive breast cancer (c/iT1-3, uni- or bilateral) at the university of rostock, who receive a primary systemic treatment and present with clinically/sonographically suspicious ipsilateral axillary lymphnodes (c/iN+) without distant metastases

Exclusion criteria

male patients, pregnancy, age <18 years, T4-tumors, distant metastases (M1)

Addresses

- **Primary Sponsor**

  Universitätsfrauenklinik am Klinikum Südstadt
  Ms. Dr. med. Steffi Hartmann
  Südring 81
  18059 Rostock
  Germany

  Telephone: **0381/44014500**
  Fax: **0381/44014599**
  E-mail: **steffi.hartmann at kliniksued-rostock.de**
  URL: **[---]***

- **Contact for Scientific Queries**

  Universitätsfrauenklinik am Klinikum Südstadt
  Ms. Dr. med. Steffi Hartmann
  Südring 81
  18059 Rostock
  Germany

  Telephone: **0381/44014500**
  Fax: **0381/44014599**
  E-mail: **steffi.hartmann at kliniksued-rostock.de**
  URL: **[---]***

- **Contact for Public Queries**

  Universitätsfrauenklinik am Klinikum Südstadt
  Ms. Dr. med. Steffi Hartmann
  Südring 81
  18059 Rostock
  Germany

  Telephone: **0381/44014500**
  Fax: **0381/44014599**
  E-mail: **steffi.hartmann at kliniksued-rostock.de**
  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)

Universitätsfrauenklinik am Klinikum Südstadt
Südring 81
18059 Rostock
Germany

Telephone: **0381/44014500**
Fax: **0381/44014599**
E-mail: **[---]***
URL: **[---]***

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.*