

## Trial Description

### Title

**Tattooing suspicious axillary lymph nodes in breast cancer patients treated by primary systemic therapy**

### Trial Acronym

**Tattoo**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The aim of the study is to investigate the feasibility of tattooing and identifying metastatic axillary lymph nodes in breast cancer patients receiving primary chemotherapy. Up to 74% of these patients of these patients convert to node negative after chemotherapy and in these cases complete axillary dissection is an overtreatment. Sentinel lymph node biopsy in these patients is not accurately enough and has low detection rates. A previous study in 12 patients has shown a detection of tattooed lymph nodes after primary chemotherapy during surgery in all cases (Choy et al. 2015). This result has to be proved in a larger number of patients. All breast cancer patients treated at the university of Rostock receiving primary chemotherapy without distant metastases can be participants of this trial. In these patients highly purified carbon solution is injected into the suspicious axillary lymphnode, which we hope to find easily during surgery.**

### Brief Summary in Scientific Language

**The aim of the study is to investigate the feasibility of tattooing and identifying metastatic axillary lymph nodes in breast cancer patients receiving primary systemic therapy. Up to 74% of these patients of these patients convert to node negative after chemotherapy and in these cases complete axillary dissection is an overtreatment. SLNB in these patients has unacceptable false-negative rates and clip-marked lymph nodes have low detection rates. A previous study in 12 patients has shown a detection of tattooed lymph nodes after primary systemic therapy during surgery in all cases (Choy et al. 2015).**

**Amendment 1 18.04.2018: number of patients n=100, multicentric study**

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

[---]\*

### Description IPD sharing plan

[---]\*



## Organizational Data

- DRKS-ID: **DRKS00013169**
- Date of Registration in DRKS: **2017/10/24**
- 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 2017-0142 , Ethik-Kommission an der Medizinischen Fakultät der Universität Rostock**

## Secondary IDs

## Health condition or Problem studied

- Free text: **breast cancer**
- ICD10: **C50 - Malignant neoplasm of breast**

## Interventions/Observational Groups

- Arm 1: **14G-Core needle biopsy and tattoing (highly purified carbon solution: 0,1-0,5ml Spot) of the largest suspicious axillary under ultrasound guidance and documentation prior primary systemic therapy**

## 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

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**detection rate of charcoal tattooed metastatic axillary lymph nodes during surgery after primary systemic therapy in breast cancer patients**

**Secondary Outcome**

- concordance of SLN and tattooed LN
- predictive value of tattooed LN for residual metastatic disease in other axillary lymph nodes
- complications caused by tattooing axillary lymph nodes (regarding injection until surgery)

**Countries of recruitment**

- DE **Germany**
- SE **Sweden**

**Locations of Recruitment**

- University Medical Center **Rostock**
- **Stockholm, Esslingen**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/07**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

## Inclusion Criteria

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

## Additional Inclusion Criteria

**All patients with primay breast cancer (c/iT1-T4c, uni- or bilateral) diagnosed at the university of Rostock, treated by primary systemic therapy presenting with suspicious axillary lymph nodes (c/i N+) without distant metastases.**

## Exclusion criteria

- **male patients**
- **pregnancy**
- **age < 18 Years**
- **distant metastases**
- **no informed consent**

## Addresses

### ■ Primary Sponsor

**Universitätsfrauenklinik Rostock  
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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

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

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URL: [---]\*

## Status

### ■ Recruitment Status: **Recruiting complete, follow-up complete**

### ■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]\*

### ■ Reason, if Reason for Recruiting Stop "Other": [---]\*

### ■ Study Closing (LPLV): **2020/04/15**

### ■ Number of Participants in Germany after Recruiting complete: **85**

### ■ Total Number of Participants (all Sites worldwide) after Recruiting complete: **117**

## 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.