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## Comparison of Axillary Sentinel Lymph Node Biopsy Versus no Axillary Surgery (INSEMA)

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

*Verified December 2015 by University of Rostock*

**Sponsor:**

University of Rostock

**Collaborators:**

German Cancer Aid (Deutsche Krebshilfe), funding  
German Breast Group (GBG Forschungs GmbH), data analysis

**Information provided by (Responsible Party):**

Toralf Reimer, MD PhD, University of Rostock

**ClinicalTrials.gov Identifier:**

NCT02466737

First received: June 4, 2015

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[History of Changes](#)

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[No Study Results Posted](#)

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### Purpose

Although there is no doubt that the presence of lymph node metastases worsens prognosis of a patient, unambiguous evidence to support lymph node dissection is still lacking. For many solid tumors, the role of lymph node dissection is yet controversial, and may depend on the tumor type and the stage of patient presentation for diagnosis. Axillary surgery for breast cancer is now considered as staging procedure that does not seem to influence breast cancer mortality. Women with breast cancer have benefitted greatly from a series of carefully performed randomized controlled trial focusing on axillary surgery. The objective of **INSEMA** is to show that less axillary surgery is better, in that oncological outcomes are the same and less surgical intervention will result in fewer surgical complications.

| <u>Condition</u> | <u>Intervention</u>  |
|------------------|--|
| Breast Cancer    | Procedure: no axillary surgery versus SLNB<br>Procedure: SLNB versus completion ALND |

Study Type: **Interventional**

Study Design: **Allocation: Randomized**

**Intervention Model: Parallel Assignment**

**Primary Purpose: Treatment**

Official Title: **Comparison of Axillary Sentinel Lymph Node Biopsy Versus no Axillary Surgery in Patients With Early-stage Invasive Breast Cancer and Breast-conserving Surgery: a Randomized Prospective Surgical Trial. Intergroup-Sentinel-Mamma (INSEMA)-Trial**

**Resource links provided by NLM:**

[Genetics Home Reference](#) related topics: [breast cancer](#)

[MedlinePlus](#) related topics: [Breast Cancer](#)

[U.S. FDA Resources](#)

**Further study details as provided by University of Rostock:**

**Primary Outcome Measures:**

- **invasive disease-free survival (IDFS) after breast-conserving surgery [ Time Frame: 5 years ] [ Designated as safety issue: No ] non-inferiority question**

Estimated Enrollment: 7095  
 Study Start Date: September 2015  
 Estimated Primary Completion Date: September 2024 (Final data collection date for primary outcome measure)

| Arms  | Assigned Interventions   |
|---|--|
| Experimental: no axillary surgery   | Procedure: no axillary surgery versus SLNB in cases with newly diagnosed breast cancer and clinically negative axillary status |
| Active Comparator: sentinel lymph node biopsy standard arm in first randomization                 | Procedure: no axillary surgery versus SLNB in cases with newly diagnosed breast cancer and clinically negative axillary status |
| Experimental: sentinel lymph node biopsy alone  | Procedure: SLNB versus completion ALND in cases with 1-2 macrometastases in sentinel lymph nodes                               |
| Active Comparator: completion axillary lymph node dissection standard arm in second randomization | Procedure: SLNB versus completion ALND in cases with 1-2 macrometastases in sentinel lymph nodes                               |

**Detailed Description:**

Currently, axillary surgery for breast cancer is considered as staging procedure that does not seem to influence breast cancer mortality, since the risk of developing metastasis depends mainly on the biological behaviour of the primary (seed-and-soil model). Based on this, the postsurgical therapy should be considered on the basis of biologic tumor characteristics rather than nodal involvement.

The goal of the present study is to show that early-stage breast cancer patients with reduced extent of axillary surgery are not inferior regarding disease-free survival outcome compared with the standard arm. All patients will be first randomized to either no axillary surgical intervention or axillary sentinel lymph node biopsy (SLNB). Patients with SLNB and pN+(sn) status will be secondly randomized to either SLNB alone or completion axillary lymph node dissection (ALND) in cases with less than three involved nodes (one or two macrometastases). Patients with three or more metastatic sentinel lymph nodes should undergo completion ALND.

Postoperative systemic treatment should be based on local multidisciplinary tumor board recommendation according to the current German AGO and S3 guidelines. For women who are treated with breast-conserving surgery, the most common site of local recurrence is the conserved ipsilateral breast itself. Thus, whole-breast radiation therapy after breast-conserving surgery is mandatory and should be performed according to the current guidelines (S3, AGO, DEGRO).

During follow-up, patients will be assessed for disease recurrence according to standard clinical practice. History and physical examination will be performed every 6 months for the first 36 months and yearly thereafter. Annual mammography and sonography will be required; other testing will be based on symptoms and investigator preference. The total number of patients to be randomized into the trial will be approximately 7,095. An event-driven final efficacy analysis will be performed per-protocol for two primary objectives.

**▶ Eligibility**

Ages Eligible for Study: 35 Years and older  
 Genders Eligible for Study: Female  
 Accepts Healthy Volunteers: No

**Criteria**

**Inclusion Criteria:**

- Written informed consent prior to beginning breast-conserving surgery, including expected cooperation of the patients for follow-up, must be obtained and documented according to the local regulatory requirements
- Histologically confirmed unilateral primary invasive carcinoma of the breast (core biopsy). Multifocal tumors are allowed if breast-conserving surgery is planned
- Age at diagnosis at least 35 years
- Preoperative imaging techniques with estimated tumor size of <5 cm (iT1/iT2 irrespective of hormone sensitivity or HER2 status)
- Clinically and sonographically tumor-free axilla prior to core biopsy (cN0/iN0)
- In cases with cN0 and iN+, a negative core biopsy or fine needle aspiration (FNA) biopsy of the sonographically suspected lymph node is required before randomization
- No clinical evidence for distant metastasis (M0)
- Planned breast-conserving surgery (R0 resection) with postoperative external whole-breast irradiation (conventional fractionation or hypofractionation)

**Exclusion Criteria:**

- Secondary malignancy, except curatively treated basalioma of the skin and carcinoma in situ of the cervix
- Time since core biopsy >3 months (optimal <1 month)
- Previous and already (neoadjuvant) treated invasive breast carcinoma
- Histologically non-invasive breast carcinoma
- cT3/T4 or iT3/T4 tumors
- Patients aged <35 years
- Planned total mastectomy (e.g. multicentric tumors )
- Planned intraoperative radiotherapy (e.g. Intrabeam) or postoperative partial breast irradiation (e.g. multicatheter technique) alone; both procedures are allowed as boost techniques
- Male patients

## ▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02466737

### Contacts

Contact: Toralf Reimer, MD, PhD +4938144014525 [toralf.reimer@med.uni-rostock.de](mailto:toralf.reimer@med.uni-rostock.de)

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### + Show 78 Study Locations

### Sponsors and Collaborators

University of Rostock

German Cancer Aid (Deutsche Krebshilfe), funding

German Breast Group (GBG Forschungs GmbH), data analysis

### Investigators

Study Chair: Toralf Reimer, MD, PhD University Medicine Rostock

## ▶ More Information

No publications provided

Responsible Party: Toralf Reimer, MD PhD, Prof. Dr. Toralf Reimer, University of Rostock  
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