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
Last updated: December 15, 2015
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History of Changes

Purpose

Although there is no doubt that the presence of lymph node metastases w orsens 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 w ith 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 w ill result in few er surgical complications.

Condition	Intervention
Breast Cancer	Procedure: no axillary surgery versus SLNB 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 allow ed as boost techniques
- Male patients

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk w ith 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

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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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Keyw ords provided by University of Rostock:
axillary surgery
sentinel lymph node biopsy

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