The clinical relevance of an armpit dissection with sparing of the nodes of the upper extrimity.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28839

Source
NTR

Brief title
ARM: Axillary Reverse Mapping

Health condition

Breast cancer, Axillary lymph node dissection, Breast cancer related lymphedema, Axillary reverse mapping

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: pink ribbon

Intervention

Outcome measures

Primary outcome

Lymphedema of the upper extrimity.

Secondary outcome

The secondary outcome measurements include other postoperative complications (pain, paresthesia, numbness and loss of shoulder mobility), quality of live and axillary recurrence ratio.

Study description

Background summary

Background:

Axillary lymph node dissection has potential negative side effects associated with the procedure including upper extremity lymphedema.1-9 Axillary reverse mapping (ARM) is a recently described technique which enables discrimination of lymphatic drainage of the breast from the arm. If upper extremity lymphedema is caused by cutting axillary lymphatic's, then being able to see and identify them would allow them to be preserved.10 The aim of this study is to determine the clinical relevance of ARM expressed by the occurrence of postoperative complications. To minimize the risk overlooking ARM node metastases, we will only include patients with an indication for a complementary axillary lymph node dissection based on a tumor-positive sentinel lymph node. Patients with an indication for an axillary lymph node dissection based on a clinical positive axilla can be included in the feasibility study to confirm the feasibility of the procedure and to perform a further subgroup analysis.

Methods and design:

280 Patients diagnosed with axillary metastasis of invasive breast cancer and an indication for a complementary axillary lymph node dissection based on a positive sentinel lymph node will be randomised to receive an axillary lymph node dissection with sparing of the ARM nodes and a standard axillary lymph node dissection. The postoperative outcome will be measured after 6,12 and 24 months. The primary outcome is the presence of breast cancer related lymphedema.
The secondary outcome measurements include other postoperative complications (pain, paresthesia, numbness and loss of shoulder mobility), quality of live and axillary recurrence ratio.

Study objective

The hypothesis is that patients undergoing an axillary lymph node dissecion with preserving of the lymph nodes and vessels of the upper extrimity (ALND-ARM) have less postoperative complications compared to patients undergoing a standard axillary lymph node dissection

(ALND-standard).

Study design

Follow-up will be performed at 6, 12 and 24 months after the primary intervention

Intervention

A standard ALND compared with a limited and more tailor-made axillary lymph node dissecion, based on the ARM technique.

Contacts

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Eligibility criteria

Inclusion criteria

Female patient aged 18 years and over presenting in one of the participating hospitals with the diagnosis invasive breast cancer and an indication for a complementary ALND based on a positive SLN are eligible for an ALND-ARM procedure. The indication for a complementary ALND will be made in a multidisciplinary team including an oncologic surgeon, medical oncologist, pathologist, radiologist and a radiotherapist.

Exclusion criteria

Primary ALND based on a clinical positive axilla, a contra-indication for SLNB, a history of (breast) cancer, an adverse event during the previous SLNB and pregnancy will be excluded from participation of the RCT.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	280
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3543
NTR-old	NTR3698
Other	METC / CCMO : 1226 / NL3920201512;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Gobardhan PD, Wijsman JH, van Dalen T, Klompenhouwer EG, van der Schelling GP, Los J, et al. ARM: axillary reverse mapping - The need for selection of patients. Eur J Surg Oncol. 2012 May 17, Epub ahead of print.