The clinical relevance of axillary reverse mapping (ARM)

Published: 21-09-2012
Last updated: 26-04-2024

The objective of the study is to determine the clinical relevance of sparing the lymfdrainage of the upper extremitiy by using the ARM-procedure in patients with breast cancer. The purpose of the continuation of the feasibility study is to create a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39541

Source
ToetsingOnline

Brief title
Clinical relevance of ARM

Condition

- Miscellaneous and site unspecified neoplasms benign
- Breast therapeutic procedures

Synonym
lymfedema, swelling

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Er is een subsidie verkregen van Pink Ribbon

Intervention

Keyword: axillary lymph node dissection, axillary reverse mapping, breast cancer, lymphedema

Outcome measures

Primary outcome

Randomisation study:

Complications will be measured after 6, 12 and 24 months after the primary procedure by a nurse practitioner/clinical investigator. The primary end-points of the study are the presence of physical complains consisting of lymphoedema, pain, numbness, loss of shoulder mobility.

Primary endpoints:

- Breast cancer related lymphoedema (BCRL)
- Paraesthesia/numbness
- Pain
- Loss of arm and shoulder mobility

Secundary endpoints:

- Quality of live
- Axillary recurrende rate

Feasibility (side-study):

- identification of ARM-nodes
- Involvement of the ARM-nodes in the metastatic proces

Secondary outcome

Randomisation study:

Secondary endpoints:

- Quality of life (QOL)

- Axillary recurrence rate

Disease free survival during the first 5-10 years will be documented during the

routinely control at the outpatient clinic.

Feasibility (side-study):

n.a.

Study description

Background summary

Axillary lymph node dissection (ALND) has potential negative side effects associated with the procedure, these include: pain, numbness or paraesthesia, swelling and arm mobility restriction.
A recently described technique makes it possible to discriminate the lymphatic drainage pattern from the breast and the arm: axillary reverse mapping (ARM). The concept of ARM is to map the drainage of the arm to determine the anatomical variation in these lymphatics and thus have a roadmap for their preservation. If arm lymph-edema is caused by cutting the axillary lymphatics, identifying them before axillary lymph node dissection (ALND) is performed would offer the possibility to preserve them.

A recently performed feasibility study in the Amphia hospital Breda, showed that it was technically feasible to perform a ARM-procedure with Blue Patent (visualization rate of 90.3%). During evaluation of the results, the patients undergoing a ALND were divided in two groups: a group which underwent a ALND secondary to a positive sentinel node procedure (SN+ group); and a group which underwent a primary ALND based on a clinical positive axillary lymphnode proven bij cytological puncture or patients with a contra-indication for a sentinel

node procedure (de CP-N+ group). After performing a ARM-procedure a standard ALND was performed (a least level I-II) in all patients. The blue colored nodes representing the arm-nodes were with separately removed and analyzed.
In the SN+group no arm-nodes showed metastasis. In the CP-N+ group the arm-nodes of 22% of the patients showed metastatic involvement. Subgroup analysis of the latter showed metastatic involvement of arm-nodes in 15.8% and 41.7% in patients which underwent neo-adjuvant chemotherapy and patients which were scheduled to get adjuvant chemotherapy respectively.
We concluded that the ARM procedure is feasible with a high visualization rate and that it is oncologic safe to safe the ARM-nodes in the SN+ group. Probably, it is even safe to spare the arm-nodes in patients who underwent neo-adjuvant chemotherapy, but these results need to be confirmed in further research.

These results are published in the European Journal of Surgical Oncology (Gobardhan et al, 2012 Epub ahead of print)

Study objective

The objective of the study is to determine the clinical relevance of sparing the lymfdrainage of the upper extremitiy by using the ARM-procedure in patients with breast cancer.

The purpose of the continuation of the feasibility study is to create a larger group of CP-N+ patients, eligble for sub-group analysis. This group consists of patients treated with neo-adjuvant chemotherapy (NAC) and adjuvant chemotherapy. The NAC group may be possible candidates for ARM-ALND as well (see results feasibility study)

Study design

Double blind randomized controlled trial.

Intervention

ALND with or without sparing of the arm lymphatics and arm nodes.

Study burden and risks

The risk excists of an extra subcutaneous injection in de upper extremity with blue patent. The risk of adverse events is limited, although a, temporary, 'blue tattoo' will exist.

The burden for the patient is that the regular outpatient clinic visits will take some extra time due to the measurements and discussion of the

questionnaires. De volume-measurement will take probably 5 minutes per arm. The questionnaires, completed by the patient, will be checked immediately.
Depending the local situation it may happen that patients will be asked for a visit, beside the regular visit. In that situation a compensation for travelling-expenses will be offered.

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818 CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818 CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female mental competent patients of at least 18 years of age with the diagnosis invasive breast cancer with an indication for a complementary axillary lymph node dissection (ALND) based on a positive sentinel lymph node (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

Exclusion criteria are: primary ALND based on a clinical positive axilla (proven by cytological punction), a contra-indication for sentinel lymph node biopsy (SLNB), a history of breast-cancer, adverse event during the previous SLNB, pregnancy.
Patients excluded for randomization between ALND and ALND-ARM will be possible candidates for the side study in which the feasibility of ARM (without sparing lymphatics and lymph nodes) is investigated.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2013
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-04-2013

Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-08-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	03-04-2014
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL39202.015.12