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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28839

Bron
NTR

Verkorte titel
ARM: Axillary Reverse Mapping

Aandoening

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

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: pink ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Lymphedema of the upper extrimity.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.