Lymphatic mapping after prior sentinel node negative breast surgery

Published: 17-06-2008
Last updated: 07-05-2024

Primary objective: To assess technical feasibility of lymphatic mapping in patients previously treated for primary breast cancer with prior surgery with a negative SNB. Secondary objectives: To determine lymphatic drainage pathways in patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON31958

Source
ToetsingOnline

Brief title
LABS-trial

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast carcinoma, breastcancer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: wetenschappelijk fonds

Intervention

Keyword: breast surgery, Lymphoscintigraphy, negative sentinel node biopsy

Outcome measures

Primary outcome

To assess technical feasibility of lymphatic mapping in patients previously

treated for primary breast cancer with surgery and a negative SNB.

Secondary outcome

To determine lymphatic drainage pathways in patients with (grossly) intact

axillary lymph nodes after prior breast surgery.

Study description

Background summary

Like in primary breast cancer, prognosis of recurrent breast cancer is also correlated with the regional lymph node status.
However, although lymphatic mapping with sentinel node biopsy is generally implemented in the clinical approach of primary breast cancer, this is not the case for recurrent breast cancer. In the latter situation, lymphatic pathways could have been altered due to prior surgery and/or radiotherapy. However, several small studies have suggested that it is feasible to perform a SNB in women who have undergone prior SNB. If lymphatic mapping and SNB truly is a valid staging procedure in locally recurrent breast cancer, it might be an alternative for complete ALND and patients may be spared a more invasive procedure and its associated morbidity. Furthermore, alternative pathways could be identified, which could lead to better staging and subsequent administration of adjuvant systemic therapy.

Study objective

Primary objective: To assess technical feasibility of lymphatic mapping in patients previously treated for primary breast cancer with prior surgery with a negative SNB.
Secondary objectives:
To determine lymphatic drainage pathways in patients with (grossly) intact

axillary lymph nodes after prior breast surgery.

Study design

This study is a prospective cohort study. Because of the descriptive instead of comparative nature of the study, randomization is not necessary.
After determining that a patient meets the inclusion criteria, informed consent is being obtained and an appointment for lymphatic mapping will be made. To minimalize patient effort this outpatient appointment will be scheduled as much as possible on the same day with regular follow-up appointments.
Lymcoscintigraphic findings will be documented for further research.

Intervention

The procedure itself consists of performing lymphoscintigraphy, similarly to the procedure done as part of the sentinel node procedure in patients with primary breast cancer, which has long been validated.
In our hospital lymphatic mapping is carried out using 99mTc-colloidal albumin (Nanocoll). Since there is no need for a SNB in this study, radioactivity won*t have to last that long and we expect one can suffice with a dose of 60Mbq of radioactive colloid.
The albumin will be injected subdermally and parenchymally at the site of the skin scar. Two hours after injection a lymphoscintigram is made. If necessary, additional recordings will be made after a greater time span has passed. The identified lymphatic drainage pathways and/or the location of the sentinel node(s) will be registered for further analysis. These lymphoscintigrams will be compared with pre-operative lymphoscintigrams of the same patient.

Study burden and risks

Lymphatic drainage could have been altered due to former surgery and/or radiotherapy. These aberrant drainage pathways could be detected with lymphatic mapping, which might be a useful tool for more accurate regional staging in the setting of recurrent breast cancer. Currently, ipsilateral axillary lymph node dissection is thought to be common clinical practice in recurrent breast cancer. If it appears to be technically feasible and valid to do lymphatic mapping and a sentinel node biopsy instead, patients could be spared a significant amount of additional morbidity in case of a negative sentinel node.
In this study, patients undergo lymphatic mapping (but no SNB) to identify changes in lymphatic drainage after prior surgery and/or radiotherapy. Outcome will be used for study purposes only and will not affect the patients possible current treatment. Radiation exposure due to lymphatic mapping consists of a dose of 0.46mSv. This is well under the constraint of 5mSv/year which is documented in the code of practice involving human research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Treated for early breast cancer with prior breast surgery (lumpectomy or mastectomy +/- radiotherapy and sentinel node procedure) with or without adjuvant systemic therapy.
- Successfully made lymphoscintigram before surgery
- Previous negative sentinel node procedure

Exclusion criteria

- Breast surgery for other reasons than breast cancer, e.g. cosmetic surgery or surgery for benign causes.)
- Complete axillary lymph node dissection
- Diagnosed with recurrent breast cancer.

- Former allergic reaction to 99mTc-colloidal albumin.
- pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL22080.060.08