

Lymphatic drainage after prior breast surgery

Gepubliceerd: 17-07-2008 Laatste bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON28452

Bron

NTR

Verkorte titel

LABS-trial

Aandoening

breast cancer
lymphatic drainage

borstkanker
lymfedrainage

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven, department of surgery.

Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Technical feasibility of lymphatic mapping

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Like in primary breast cancer, prognosis in recurrent breast cancer is correlated with regional lymph node status. Therefore, axillary staging may be warranted in patients with recurrent disease and intact axillary nodes, although this has not been described in guidelines yet. The lymphatic drainage pathways in the breast and/or axilla could have been changed due to prior surgery and/or radiotherapy. These aberrant drainage pathways could be detected with lymphatic mapping and sentinel node biopsy (SNB), leading to a more accurate staging.

Objective:

To assess the technical feasibility of lymphoscintigraphy after prior breast surgery (PBS). A second goal is to investigate whether or not previous breast surgery (with or without radiotherapy) significantly changes the lymphatic drainage pathways of the breast.

Study design:

A prospective cohort study.

The intention is to include 50 women above 18 years who underwent PBS in the setting of breastcancer between 01/01/2002 and 31/12/2007. From all included patients a lymphoscintigram will be made which will be compared with pre-operative lymphoscintigram in order to detect changes in lymphatic drainage pathways.

Main study parameters/endpoints:

To assess the technical feasibility of lymphatic mapping in patients who underwent PBS for primary breast cancer. Identification of lymphatic drainage pathways in patients who received PBS.

Doel van het onderzoek

N/A

Onderzoeksopzet

We will evaluate the lymphatic drainage at 1, 3, or 5 years after surgery and/or completement of radiotherapy.

The actual lymphoscintigram will be made at +/- 2 hours after injection of radioactive colloid.

Onderzoeksproduct en/of interventie

Injection of radioactive colloid

Contactpersonen

Publiek

Catharina Ziekenhuis

Department of surgery

Postbus 1350

5602 ZA Eindhoven
K. Woensdregt
Catharina Ziekenhuis
Michelangelolaan 2

Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2399111

Wetenschappelijk

Catharina Ziekenhuis

Department of surgery

Postbus 1350

5602 ZA Eindhoven
K. Woensdregt
Catharina Ziekenhuis
Michelangelolaan 2

Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2399111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Treated for early breast cancer with prior breast surgery, with or without adjuvant systemic therapy between 01/01/2002 and 31/12/2007.
2. Primary tumor localisation in upper-outer, upper-inner, under-outer, under-inner quadrant or peri-areolar
3. Successfully made lymphoscintigram before surgery
4. Prior successful sentinel node procedure with negative sentinel node

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Breast surgery for other reasons than breast cancer
2. Complete axillary lymph node dissection
3. Diagnosed with recurrent breast cancer
4. Former allergic reaction to 99Tc-colloidal albumin
5. Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2008
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	17-07-2008
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	NL1325
NTR-old	NTR1385
Ander register	NL22080.060.08 : M08-1816
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A