Sentinel Node And Recurrent Breast cancer

No registrations found.

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

Summary

ID

NL-OMON22722

Source
Nationaal Trial Register

Brief title
SNARB

Health condition

Recurrent breast cancer
Sentinel node biopsie

Recidief mammacarcinoom
Schildwachtklierprocedure

Sponsors and support

Primary sponsor: The principal investigator of this study is mrs. A. Maaskant-Braat, resident surgery
Source(s) of monetary or material Support: This research is not sponsored;it is self-financed.

Intervention

Outcome measures

Primary outcome

- Registration of technical feasibility of lymphatic mapping and sentinel node biopsy in patients with locally recurrent breast cancer.

- Registration of success rate of lymphatic mapping and SNB in patients with locally recurrent breast cancer.

- Registration of validity of lymphatic mapping and sentinel node biopsy in patients with locally recurrent breast cancer.

Secondary outcome

- Registration of lymphatic drainage pathways in patients with locally recurrent breast cancer.

- Registration of sentinel lymph node status in patients with locally recurrent breast cancer.

- Registration of possible influence of lymphatic mapping and SNB on therapeutic decisions in patients with locally recurrent breast cancer.

Study description

Background summary

Rationale:

Like in primary breast cancer, prognosis in recurrent breast cancer is correlated with regional lymph node status. Therefore, it seems sensible to perform lymphatic staging in case of an intact axillary lymph node basin, although this has not been described in guidelines yet. Due to surgery and radiotherapy lymph drainage pathways could be altered. These aberrant drainage pathways could be detected with lymphatic mapping and sentinel node biopsy leading to a more thorough staging and possible change in treatment strategy.

Objective:

To propose a regional staging protocol, lymphatic mapping and sentinel node biopsy, for patients with locally recurrent breast cancer in the absence of guidelines for regional staging procedures and to registrate data derived from this study.

Study design:

A prospective, multicenter, national registration study.

Study population:
At least 150 women above 18 years old with locally recurrent breast cancer after earlier BCT or modified radical mastectomy.

Main study parameters/endpoints:
Registration of technical feasibility and validity of lymphatic mapping and sentinel node biopsy in patients with locally recurrent breast cancer as well as registration of lymphatic drainage pathways and sentinel lymph node status. Furthermore, the influence of this staging procedure on therapeutic decisions will be evaluated.

Study objective

Due to surgery and radiotherapy lymph drainage pathways in recurrent breast cancer could be altered. These aberrant drainage pathways could be detected with lymphatic mapping and sentinel node biopsy leading to a more thorough staging and possible change in treatment strategy.

Study design

- Pre-operative inclusion

- Operation

- Post-operative registration: first post-operative consult

Intervention

Lymfatic Mapping and sentinel lymph node biopsie.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women above 18 years old with locally recurrent breast cancer after earlier BCT or modified radical mastectomy.

2. Operable cytological /histological confirmed locally recurrent breast cancer.

3. Having obtained an informed consent.

Exclusion criteria

1. Proven ipsi- or contralateral regional lymph node metastases (ultrasound and FNA).

2. Known to be allergic to “99mTc-colloidal albumin” or blue dye injection fluids.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion Date:	18-09-2008
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	NL1390
NTR-old	NTR1450
Other	NL 19199.060.07 : M07-1792
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A