Sentinel Node and Recurrent Breast Cancer; Regional staging proposal and registration

Published: 28-01-2008
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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.

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

Summary

ID

NL-OMON33553

Source
ToetsingOnline

Brief title
SNARB

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Recurrent mammacarcinoma; breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Wetenschappelijke fondsen

Intervention

Keyword: Recurrent breast cancer, Sentinel node procedure

Outcome measures

Primary outcome

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.

Secondary outcome

Not applicable

Study description

Background summary

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.

Study 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 burden and risks

When performing lymphatic mapping and SNB, patients could be spared a significant amount of additional morbidity in case of a negative sentinel node. Furthermore, lymphatic drainage could have been altered due to former surgery and/or radiotherapy. These aberrant drainage pathways can be detected with lymphatic mapping and SNB leading to a more thorough staging. In this study, patients undergo an additional sentinel node procedure next to surgery and, if necessary, ipsilateral axillary lymph node dissection. Risks involve the very small possibility of anaphylaxis to *99mTc-colloidal albumin* or blue dye injection fluids. Radiation exposure due to lymphatic mapping is negligible.

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

-Operable cytological /histological confirmed locally recurrent breast cancer
-Having obtained an informed consent

Exclusion criteria

-Proven ipsi- or contralateral regional lymph node metastases (ultrasound and FNA)
-Known to be allergic to *99mTc-colloidal albumin* or blue dye injection fluids

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	28-01-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2010

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-10-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-12-2010
Application type:	Amendment
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	NL19199.060.07