SMMaC trial: a prospective validation study of Sentinel lymph node biopsy in patients with Multicentric Mamma Carcinoma.

Published: 23-01-2008
Last updated: 11-05-2024

The objective of this study is to determine the accuracy of the sentinel lymph node biopsy in multicentric breast cancer prospectively and multi-institutional.

Ethical review	-
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35626

Source
ToetsingOnline

Brief title
SMMaC trial: SLN biopsy in Multicentric Mamma Carcinoma.

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
at least 2 malignant breast tumors at multiple sites in one breast; multicentric breast cancer

Health condition

borst diagnostische verrichtingen

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: accuracy, axillary metastases, multicentric breast cancer, sentinel lymph node biopsy

Outcome measures

Primary outcome

- successful identification of sentinel lymph nodes

- mean number of excised sentinel lymph nodes

- number of true positive sentinel lymph nodes

- number of positive non-sentinel lymph nodes at axillary lymph node dissection

o False negative rate= number of false negative SNs/ true positive+ false

negative nodes x 100.

o Sensitivity= true positive/ true positive + false negative x 100

o Negative predictive value= true negative / true negative + false negative x

100

o Accuracy= true positive + true negative/ successful SNBs x 100.

o Likelihood ratio for negative test results=m(1- sensitivity)/ specificity

Secondary outcome

None

Study description

Background summary

Multicentric tumors have been considered a contraindication for SLN biopsy due to the possible higher false negative rate (identification of the **wrong** SLN). However, recent studies support the theory that the lymphatic pathways from different sites of the breast converge into one major lymphatic trunk affering to the same SLN(s).

Study objective

The objective of this study is to determine the accuracy of the sentinel lymph node biopsy in multicentric breast cancer prospectively and multi-institutional.

Study design

Patients with preoperative diagnosis of multicentric breast carcinoma, identified between July the 1st of 2008 and July the 1st of 2010 will undergo a sentinel lymph node biopsy.
Lymphatic mapping with SLNB will be performed by peri-areolar intradermal injection of 0,1- 0,2 ml of 25 MBq Tc-99m nanocolloid and Patent Blue dye at 4 sites. All patients will undergo a standard axillary lymph node dissection. The accuracy of the sentinel lymph node biopsy will be determined.

Study burden and risks

Sentinel lymph node biopsy is a minimally invasive method to determine the tumorstatus of the axilla.

Radiation exposure:
The radio-isotope 99m Technetium is a relatively short living radio-isotope with a gammaradiation energy of 140 KeV. The half-life is 6,02 hours, which means that the amount of radioactivity is half of the original amount after 6 hours. After 18 hours there is only 1/8 of the amount of original activity left in the patient.

Thus:
- T= 0 intracutaneous injection (20 hours preoperatively) of 25 MBq 99m-Technetium nanocolloid in 4 x 0,1 to 0,2 ml
- T= 17 hours scan (day of operation)
- T= 20 hours operation

When surgery starts three half-lifes have passed and there is less than 12,5

MBq left in the patient.
The radiation exposure for the patient is 2,1 mSV at a given dosis 100 MBq Tc-99m nanocolloïd. For a surgeon this is 0,5 µS.

Contacts

Public
Jeroen Bosch Ziekenhuis

Postbus 90153
5200 ME 's Hertogenbosch
NL
Scientific
Jeroen Bosch Ziekenhuis

Postbus 90153
5200 ME 's Hertogenbosch
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients with a preoperative diagnosis of multicentric infiltrating breast carcinoma
- at least 2 positive lesions
- clinically node negative (cN0) breast carcinoma
- also T2-T3 cancers

Exclusion criteria

- ductal or lobular in situ carcinomas
- clinical and/or echographic evidence of positive axilla
- neoadjuvant chemotherapy
- previous ipsilateral breast or axillary surgery
- preoperative radiotherapy
- distant metastases
- pregnant women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	28-10-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-02-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-03-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	05-04-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL20280.028.07