Towards plannable breast surgery: Diagnostic accuracy of microbubble enhanced Iodine-125 seed localization of the sentinel lymph node.

No registrations found.

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

Summary

ID

NL-OMON27431

Source
NTR

Brief title
MIB study

Health condition

Breast cancer, sentinel lymph node localization

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Department of Radiology
Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

Detection rate of microbubble-enhanced Iodine-125 seed localization of SLN, defined as the

number of patients in whom the microbubble-enhanced SLN and the Tc-99m enhanced SNL are the same.

Secondary outcome

1. Sensitivity of microbubble-enhanced I-125 seed localization;

2. Technical feasibility: visualization of SLN, successful I-125 seed placement and excision of I-125 seed without migration or seed loss;

3. Preoperative concordance of microbubble and Tc-99m enhanced SLNs, imaged with SPECT/CT;

4. Duration of procedures and hospitalization;

5. Patients pain and comfort scores: Microbubble-enhanced versus Tc-99m guided localization of SLN;

6. Surgeon’s / radiologists preferences and opinions.

Study description

Background summary

Preoperative work-up for breast surgery and sentinel lymph node (SLN) biopsy is logistically complicated. On the day of surgery, patients spend hours at imaging departments and operating theatres are forced to keep flexible time schedules. Microbubble-enhanced Iodine-125 seed localization has the potential to allow localization of the SLN days or weeks before surgery. With the current study, we aim to evaluate whether microbubble localization of the SLN is a reliable alternative for the standard technetium-99m enhanced SLN localization and subsequent SLN biopsy. If the microbubble technique turns out to be an accurate alternative, logistics and waiting time on the day of surgery will be improved, which would be of great benefit for the patient.

Study objective

Contrast-enhanced ultrasound with microbubbles will localize the same axillary lymph node as Technetium-99m nanocolloid.

Study design

SLN localization with microbubbles, Iodine-125 seed placement and SPECT/CT scan.

Intervention

Preoperative contrast-enhanced ulterasound with microbubble contrast for localization of axillary lymph node(s) localization with subsequent placement of an Iodine-125 seed will be compared to 'standard sentinel lymph node localization'. Both techniques will be applied in all study patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Females, aged 18 years or older;

2. Histologically confirmed invasive carcinoma or patients with in situ breast cancer with indication for SLN biopsy.

Exclusion criteria

1. Male patients;

2. Histologically or cytologically proven axillary lymph node involvement;

3. Recurrent disease;

4. Indication for ALND;

5. Pregnancy or lactation;

6. Sentinel lymph node biopsy after neoadjuvant treatment;

7. Recent acute coronary syndrome or unstable ischemic heart disease*;

8. Severe lung disease* and shortness of breath;

9. Unstable neurologic disease, acute endocarditis, artificial heart valves, acute systemic infection, tromboembolic disease, advanced liver or kidney failure;

10. Mentally incompetent patients.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	29-09-2012
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-10-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37670
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3535
NTR-old	NTR3690
CCMO	NL38677.041.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37670

Study results

Summary results

1) Sever AR, Mills P, Jones SE, Mali W, Jones PA. Sentinel node identification using microbubbles and contrast-enhanced ultrasonography. Clin Radiol. 2012 Jul;67(7):687-94. Epub 2012 Jan 9.
2) Sever AR, Mills P, Jones SE, Cox K, Weeks J, Fish D, Jones PA. Preoperative sentinel node identification with ultrasound using microbubbles in patients with breast cancer. AJR Am J Roentgenol. 2011 Feb;196(2):251-6.