

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

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27431

Bron

Nationaal Trial Register

Verkorte titel

MIB study

Aandoening

Breast cancer, sentinel lymph node localization

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, Department of Radiology

Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Preoperative contrast-enhanced ultrasound 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Females, aged 18 years or older;
2. Histologically confirmed invasive carcinoma or patients with in situ breast cancer with indication for SLN biopsy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	29-09-2012
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37670

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

- 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.