Gamma Probe and Ultrasound Guided Fine Needle Aspiration Cytology of the Sentinel Node Trial

No registrations found.

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

Summary

ID

NL-OMON21922

Source
Nationaal Trial Register

Brief title
GULF

Health condition

Melanoma, Breast Cancer, Sentinel Lymph Node Biopsy, FNA/FNAC, Surgery

Melanoom, Mammacarcinoom, Schildwachtklierbiopsy, FNA, Chirurgie

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Outcome measures

Primary outcome

Sensitivity of combined gamma probe and ultrasound guided FNAC of the SN

Secondary outcome

1) SN identification rate >75%

2) Histological results of core needle biopsy versus sentinel node biopsy (surgery) and versus FNAC.

Study description

Background summary

Sentinel node biopsy detects clinically occult metastases of breast cancer and melanoma in 20-30%. The remaining 70-80% of patients remain negative, but nonetheless are exposed to potential morbidity in up to 10%, consisting of wound infections, seroma and even lymph edema.
Ultrasound imaging to detect metastases in the sentinel node is not accurate enough to replace surgical removal of the sentinel node. Additional use of the standard peroperatively used gamma probe has been reported to improve the identification rate of the sentinel node, enabling the possibility to accurately perform FNAC.
This study aims to provide a minimally invasive alternative for surgical sentinel node biopsy, combining use of a gamma probe and ultrasound for FNAC of the sentinel node in melanoma and breast cancer patients.

Study objective

Gamma probe and ultrasound guided fine needle aspiration cytology (FNAC) of the sentinel node (SN) is an accurate and sensitive minimally invasive alternative to the gold standard of surgical resection of the sentinel node in melanoma and breast cancer patients.

Study design

Estimated inclusion: 2 years.

Intervention

All: preoperative gamma probe and ulstrasound guided FNAC of the sentinel node (SN).

First 10 Breast cancer patients: additional core needle biopsy of SN

First 10 patients (excluding first 10 breast cancer patients): additional marker placement in SN

Contacts

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Eligibility criteria

Inclusion criteria

- New diagnosis of cT1b-4N0M0 cutaneous melanoma or cT1-3N0M0 breast cancer

- Age ≥ 18 years

Exclusion criteria

- Clinically suspect lymph node

- Other known malignancy with potential to disseminate to axillary or groin lymph node basins.

- Prior lymph node biopsy

- No SN visible at lymphoscintigraphy / not identifiable with gamma probe.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-05-2015
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41742
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5062

Register	ID
NTR-old	NTR5193
CCMO	NL52091.078.15
OMON	NL-OMON41742

Study results