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

Published: 13-04-2015
Last updated: 15-05-2024

To study the sensitivity of the combined gamma probe and US guided FNA compared to the gold standard histology of the surgically removed SNB. Secondary aims 1) to study the identification rate of this technique 2) to study possible differences in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON41742

Source
ToetsingOnline

Brief title
GULF trial

Condition

- Metastases
- Skin neoplasms malignant and unspecified
- Haematological and lymphoid tissue therapeutic procedures

Synonym
melanoma & breast cancer lymph node metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Subsidie Stichting Coolsingel

Intervention

Keyword: FNA, Gamma-probe, Sentinel node

Outcome measures

Primary outcome

Feasibility of this intervention is evaluated by assessment of the sensitivity.

A sensitivity of at least 90% is favoured.

Secondary outcome

1. A reproduction of reported identification rates (75-100%) is pursued.

2. Comparison of histological results of CNB versus SNB and versus FNA.

Study description

Background summary

Sentinel node biopsy (SNB), which is a surgical operation, is the gold standard for staging of melanoma and breast cancer patients. Given the invasive nature of this staging procedure, there is a morbidity rate of up to 10% associated with SNB, mostly consisting of seroma and wound infection / dehiscence, and rarely lymph edema. Targeted ultrasound (US) of the sentinel node (SN), with or without fine needle aspiration cytology (FNA) have recently been investigated as minimally invasive alternatives. However, reported sensitivity rates so far are too low to replace SNB, due to a low identification rate of the SN and a high false negativity rate. Our hypothesis is that additional use of a handheld gamma-detection probe can aid in transcutaneous identification of the SN for FNA or core needle biopsy (CNB), thereby providing a minimally invasive SN procedure which ultimately even may replace surgical SNB.

Study objective

To study the sensitivity of the combined gamma probe and US guided FNA compared to the gold standard histology of the surgically removed SNB. Secondary aims 1) to study the identification rate of this technique 2) to study possible differences in outcome of FNA vs CNB.

Study design

Open single arm observational study with invasive measurements.

Intervention

All patients will undergo intervention in addition to standard care. The intervention consists of preoperative gamma probe and US guided detection of the SN to perform FNA. The first 10 patients additionally receive placement of a titanium marker in the SN for identification rate control. Separately, additional CNB is performed in the first 10 breast cancer patients to study histological compatibility of CNB vs SNB.

Study burden and risks

Only minimal risks are associated with participation in this study. Minimal burden to the patient is caused by undergoing US and FNA (which takes 20 minutes) in the time frame between preoperative lymphoscintigram and SNB. The first 10 patients will additionally receive placement of a titanium marker for SN identification rate control (10 more minutes). Separately, the first 10 breast cancer patients receive an additional CNB (10 more minutes). No extra visits or repeat visits are needed. Both FNA and CNB are known as minimally invasive procedures, as the most frequent complications are minor (haematoma or minimal prolonged bleeding at the puncture site) and occur in less than 1%, and both FNA and CNB are preferred procedures for staging primary breast cancer tumours and metastases of both breast cancer and melanoma. Titanium marker placement is minimally invasive as well, being increasingly applied in combination with CNB for localization of the primary tumor in breast cancer. Concluding, we feel that the extra burden for these patients is outweighed by the possible benefit for future patients who can be spared a SNB and its complications.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
Rotterdam 3075EA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301

Rotterdam 3075EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

New diagnosis of cT1b-4N0M0 melanoma or cT1-3N0M0 breast cancer, >/<= 18 years old.

Exclusion criteria

- Clinically suspect lymph node
- Other known malignancy with potential to disseminate to axillary or groin lymph nodes
- Prior lymph node biopsy
- No SN visible at lymphoscintigraphy

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):	26-05-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	13-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21922
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52091.078.15
OMON	NL-OMON21922