INTRAOPERATIVE REAL TIME IMAGING WITH A DUAL RADIOACTIVE/FLUORESCENCE MODALITY FOR SENTINEL NODE LOCALIZATION. A FEASIBILITY STUDY INCLUDING REPRODUCIBILITY OF MULTIMODALITY LYMPHATIC MAPPING WITH A COCKTAIL TRACER CONTAINING 99mTc NANOCOLLOID /ICG

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1. To explore whether the intraoperative combination of a portable gamma camera for real time imaging and a 99mTc nanocolloid/ICG cocktail for simultaneous radioactive and fluorescence detection is suitable to retrieve sentinel nodes in difficult...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON33218

Source
ToetsingOnline

Brief title
RADIOACTIVE/FLUORESCENCE MODALITY FOR SENTINEL NODE LOCALIZATION.

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI/AVL

Intervention

Keyword: fluorescence, lymphoscintigraphy, portable gamma camera, sentinel node

Outcome measures

Primary outcome

1.number and location of sentinel nodes after 99mTc-nanocolloid injection

2.number and location of sentinel nodes after cocktail injection

3.different locations and number of sentinel nodes after first injection

4.surgical retrieval rate and procedure time

Secondary outcome

None

Study description

Background summary

Lymphoscintigraphy can determine the lymphatic pattern and the location of the lymph nodes with direct drainage from the tumor site, the sentinel nodes. The sentinel node is likely to be the first node to harbor tumor cells, which may lead to change the patients* management. Preoperative lymphoscintigraphy in combination with intraoperative blue dye and gamma probe detection has led to

sentinel node retrieval rates of 99% in melanoma and more than 95% in breast cancer, in the past 15 years. The technique has been adopted for other malignancies for better staging and to diminish the morbidity of the standard surgical approaches. However, in some conditions sentinel nodes are difficult to be found. This is the case for sentinel nodes located in the neck in patients with cutaneous melanoma and oral cavity malignancies. Also in patients with melanomas of the upper part of the trunk sentinel nodes may be located in areas difficult to explore. Finally, in almost a third of breast cancer patients sentinel nodes outside of the axilla are seen and in only 80% of the cases these sentinel nodes can be retrieved. Against this background the introduction of a portable gamma camera for real time intraoperative imaging and a 99mTc-nanocolloid tracer and Indocyanine Green (ICG) cocktail for simultaneous radioactive and fluorescence detection may enable the localization of sentinel nodes difficult to retrieve. In the present study we will explore the feasibility of this diagnostic combination in patients with melanoma of the head/neck or the upper part of the trunk, patients with oral malignancies and patients with a medially located breast tumor and demonstrated lymphatic drainage outside the axilla. At the same time we will assess the reproducibility of the lymphatic drainage using the tracer cocktail in comparison with the patterns of the standard 99mTc -nanocolloid.

Study objective

1. To explore whether the intraoperative combination of a portable gamma camera for real time imaging and a 99mTc nanocolloid/ICG cocktail for simultaneous radioactive and fluorescence detection is suitable to retrieve sentinel nodes in difficult anatomical areas in patients with malignancies characterized by superficial drainage patterns.
2. To establish the reproducibility of the 99mTc nanocolloid/ICG cocktail in comparison to the standard 99mTc -nanocolloid.

Study design

This is a prospective feasibility study involving cancer patients scheduled for sentinel node localization in areas of difficult surgical exploration. In this study intraoperative sentinel node localization using a portable gamma camera and a dual-labeled 99mTc/ICG tracer will be performed in addition to the standard sentinel node procedure. At the same time lymphatic patterns of 99mTc-nanocolloid and the cocktail will be compared. The hypothesis to be tested is that this diagnostic combination will be reproducible, suitable and effective in the localization of the sentinel node in anatomical areas with a recognised surgical difficulty degree.
The patients will be investigated in addition to the standard sentinel node procedure by re-injecting the dual-tracer. Subsequently patients will be operated within 4 hours after tracer administration. Sentinel node retrieval rates will be recorded and both the length of the surgical procedure and the

acceptation degree by the surgeon will be evaluated using special formularies. Furthermore early gamma camera images of both tracers will be compared for reproducibility. It is expected that fluorescent sentinel node visualisation rates will be similar to radioactive sentinel node rates for melanoma and oral cavity malignancies. In the case of internal mammary sentinel nodes it is expected that fluorescent sentinel node rate (>90%) will be significantly higher than blue dye (30%). It is also expected that sentinel node retrieval rate will be more than 90% in all patient categories.

Study burden and risks

Allergic reactions or other adverse effects following administration of 99mTc-nanocolloid have not been described. The total dosage of radioactivity is within the limits that are recommended.
Allergic reactions to the fluorescence component ICG in the cocktail are not expected. ICG is a FDA approved agent for human use. This compound has been safely applied in humans.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients presenting cutaneous melanoma of head/neck and upper part of the trunk
Patients presenting oral cavity malignances T1-2N0
Breast cancer patients with a medially located tumor (palpable tumors and non-palpable tumors detectable by ultrasound) with demonstrated drainage outside the axilla
Patients with clinical N0 stage

Exclusion criteria

Evidence of regional or distant metastases
Non-palpable breast tumors requiring stereotaxis for tracer administration
Incapacity or unwillingness of participant to give written informed consent
Allergy to iodides

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	25-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL26699.031.09