Multicenter study evaluating the hybrid approach using a novel fluorescence camera - Identifying the value of intraoperative fluorescence imaging during sentinel node biopsy procedures

Published: 16-12-2016
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Primary objectives:- Determine the value of fluorescence imaging-guided surgery under ambient light conditions for the identification of hybrid tracer-containing SNs as seen on preoperative imaging.Secondary objectives:- Determine the value (...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47277

Source
ToetsingOnline

Brief title
Evaluating the hybrid approach during sentinel node biopsy

Condition

- Other condition

Synonym
sentinel node biopsy

Health condition

schildwachtklierprocedure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-STW-VIDI (STW BGT 11272) ,ERC-starting grant (2012-306890)

Intervention

Keyword: fluorescence, hybrid, imaging, sentinel node

Outcome measures

Primary outcome

- Determine the value of fluorescence imaging-guided surgery under ambient light conditions for the identification of hybrid tracer-containing SNs as seen on preoperative imaging.

Secondary outcome

- Determine the value (accuracy) of fluorescence imaging-assisted SN identification to the conventional radioguided approach;

- Determine the value of fluorescence imaging-assisted SN identification to the conventional blue dye-based approach;

- Evaluation of (post-operative) complications within 90 days after surgery (Clavien-Dindo score);

- Evaluation of follow-up (local recurrence after SN biopsy).

Study description

Background summary

The sentinel node biopsy procedure is conventionally performed via a

radioguided surgery approach. Upon the injection of a radiolabeled colloid preoperative imaging is performed to determine the number and location of the sentinel nodes. Intraoperatively then a gamma-ray detection probe is used to guide the surgeon to the radioactive nodes. However, this approach does not always allow optical sentinel node identification. Therefor, prior to the start of the operation often a blue dye is injected. But, we have experienced that blue dye does not always stain the node(s) blue. Therefore, in 2001, as a blue dye alternative, the near-infrared fluorescence dye indocyanine green (ICG) was introduced.
Recently we showed that using the hybrid tracer ICG-99mTc-nanocolloid, dthe advantages of the conventional radioguided procedure could be combined with the advantages of near-infrared fluorescence imaging. In feasibility studies we found that using this hybrid approach, preoperative imaging findings could be directly translated in to the operation room. Moreover, it was found that the hybrid tracer significantly outperformed blue dye in terms of optical sentinel node identification. However, for effective fluorescence imaging, lights in the operation theatre have to be dimmed. This has resulted in fluorescence imaging being used a confirmatory imaging modality. In a recent pilot study we then evaluated a fluorescence camera that works under ambient light conditions. Nevertheless, the value of this approach during the operation (for the patient and the operating surgeon) remains to be investigated.

Study objective

Primary objectives:
- Determine the value of fluorescence imaging-guided surgery under ambient light conditions for the identification of hybrid tracer-containing SNs as seen on preoperative imaging.

Secondary objectives:
- Determine the value (accuracy) of fluorescence imaging-assisted SN identification to the conventional radioguided approach;
- Determine the value of fluorescence imaging-assisted SN identification to the conventional blue dye-based approach;
- Evaluation of (post-operative) complications within 90 days after surgery (Clavien-Dindo score);
- Evaluation of follow-up (local recurrence after SN biopsy).

Study design

A total of 670 patients will have to be included, of which 125 will be included from the Netherlands. The number and location of the sentinel node(s) will be determined following the hybrid tracer injection and preoperative imaging (current routine). Intraoperatively, firstly fluorescence guidance will be used to identify the sentinel node(s). If this is not successful within 15 min, the conventional approach of radio- and fluorescence and blue dye guidance will be

used to identify the sentinel node(s).

Intervention

On the morning of surgery, ICG-99mTc-nanocolloid will be injected peri- or intratumorally Lymphoscintigrams and SPECT/CT imaging will be performed to determine the number and location of the sentinel node(s).
Intraoperatively, after anesthetizing the patient, sentinel node biopsy will be performed. During the first 15 min only fluorescence guidance will be used. If this does not result in sentinel node identification, the conventional approach of radio- and fluorescence and blue dye guidance will be used.
Ex vivo, for each removed sentinel node, the gamma probe status (amount of radioactivity in the node) and the fluorescence status (y/n fluorescence in the node) will be documented. Sentinel nodes will be assessed following the standard sentinel node protocol at the department of pathology department.
Subsequently, after completion of the operation, the operating surgeon will be asked to fill in a questionnaire to evaluate the value of fluorescence guidance during the operation.

Study burden and risks

The value of fluorescence guidance during the sentinel node biopsy procedure will be evaluated. Findings will be compared to the conventional approach.

Because initially sentinel nodes will be pursued using fluorescence guidance only, anesthesia will be prolonged with 15-20 min.

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 >= 18 years;
- Patients with a primary or recurrent breast cancer;
- Patient with a primary melanoma;
- Patients with a primary head-and-neck malignancy;
- Patient with a primary or recurrent urological malignancy;
- Patients with a primary or recurrent gynecological malignancy;
- Patients present with negative regional lymph nodes (exception: vulvar and penile cancer: N1 patients are also eligible);
- Patients that will undergo a sentinel node biopsy procedure.

Exclusion criteria

- History of iodine allergy;
- Hyperthyroid or thyroidal adenoma;
- Kidney insufficiency;
- Pregnant women.

Study design

Design

Study phase:	2
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-07-2018
Enrollment:	125
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	indocyanine green - technetium 99m - nanocolloid
Generic name:	ICG-99mTc-nanocolloid

Ethics review

Approved WMO Date:	16-12-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-06-2018
Application type:	Amendment
Review commission:	METC NedMec

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
EudraCT	EUCTR2016-003262-42-NL
CCMO	NL58854.031.16