A prototype opto-nuclear probe for combined radio- and fluorescence tracing of the sentinel node

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Primary objective:- Determination of the sensitivity and specificity of the open-procedure opto-nuclear probe for sentinel node(s) identification using the combination of radio- and fluorescence tracing. Obtained results will be compared to those...

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

Summary

ID

NL-OMON40822

Source
ToetsingOnline

Brief title
A prototype opto-nuclear probe for sentinel node biopsy

Condition

- Other condition

Synonym
sentinel node biopsy

Health condition

schildwachtklieronderzoek bij hoofd-hals maligniteiten (M/V), penis en prostaat kanker

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),Eurorad (leverancier opto-nuclear probe)

Intervention

Keyword: fluorescence tracing, gamma tracing, lymph node, sentinel node

Outcome measures

Primary outcome

The intraoperative sentinel node identificaton rate using the opto-nuclear

probe via 1) gamma tracing; and 2) via fluorescence tracing. Obtained results

will be compared tot hat of the gamma camera and the fluorescence camera

(routinely used methods).

Secondary outcome

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Study description

Background summary

Recent developments in the field of image-guided surgery have resulted in the introduction of fluorescent tracers into the clinic. For optical sentinel node identification, the near-infrared fluorescence tracer indocyanine green (ICG) was introduced. However, it does not allow for preoperative sentinel node mapping; the limited tissue penetration of the fluorescence signal prohibits this. With the introduction of a hybrid tracer, in which ICG is coupled to the conventional radiocolloid 99mTc-nanocolloid, our group showed that both preoperative sentinel node mapping and fluorescence sentinel node identification is possible with a single tracer.
To surgically detect the radioactive and the fluorescent signal, intraoperatively generally a gamma probe (detection radioactive signal) and a fluorescence camera (detection fluorescent signal) are used for sentinel node identification. To further improve these logistics, the company Eurorad developed a prototype opto-nuclear probe that is able to detect both the

radioactive and the fluorescent signal. This way, it becomes possible to detect hybrid, combined radioactive and near-infrared fluorescent, tracers using a single imaging modality.

Study objective

Primary objective:
- Determination of the sensitivity and specificity of the open-procedure opto-nuclear probe for sentinel node(s) identification using the combination of radio- and fluorescence tracing. Obtained results will be compared to those obtained using the conventional method(s);
- Determination of the sensitivity and specificity of the laparoscopic opto-nuclear probe for sentinel node(s) identification using the combination of radio- and fluorescence tracing. Obtained results will be compared to those obtained using the conventional method(s).

Secondary objective:
- Identification of (tumor positive) sentinel node(s) using the opto-nuclear probe for open procedures;
- Identification of (tumor positive) sentinel node(s) using the opto-nuclear probe for laparoscopic procedures;
- Obtaining the CE-mark for the opto-nuclear probe for open procedures;
- Obtaining the CE-mark for the opto-nuclear probe for laparoscopic procedures.

Study design

30 Patients will be prospectively included in this study. The number and location of the sentinel node(s) will be determined following the hybrid tracer injection and preoperative imaging (current routine). Intraoperatively, a prototype opto-nuclear probe will be used for sentinel node identification. Findings of this prototype will be compared to that of the conventional standards (gamma camera and fluorescence camera).

Intervention

According to the current standard, on the afternoon prior to, or on the morning of surgery, ICG-99mTc-nanocolloid will be injected peritumorally sub- or intracutaneously (patients with prostate cancer will be injected intraprostatically). Lymphoscintigrams and SPECT/CT imaging will be performed to determine the number and location of the sentinel node(s).
Sentinel node biopsy will be performed after general or regional anesthesia using the opto-nuclear probe. Firstly, sentinel nodes will be pursued via their radioactive signature. After localizing the sentinel node, the mode of the opto-nuclear probe will be switched to the fluorescence setting. Thereafter, fluorescence tracing to the sentinel node will be performed. After localization using the opto-nuclear probe, the conventional methods (gamma camera and

fluorescence camera) will be used to evaluate the accuracy.
For each removed sentinel node, the gamma probe status (amount of radioactivity in the node) and the fluorescence status (amount of fluorescence in the node) will be documented. Sentinel nodes will be assessed following the standard sentinel node protocol at the pathology department.

Study burden and risks

Ultimately the proposed research will lead to the intraoperative use of one modality that allows for combined gamma- and fluorescence tracing instead of the need of various modalities. This may lead to improved logistics and a reduced operation time.

Due to the proposed research, patients will be kept under anesthesia for an extra 10-15 minutes.

Risk-analysis revealed no (in)direct risks for the intraoperative use of the opto-nuclear probe.

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 of age;
- Patients with histologically proven head and neck malignancies;
- Patients with histologically proven penile cancer;
- Patients with histologically proven prostate cancer;
- Patients are clinically N0M0 (penile cancer: N0M0 or N1M0);
- For head and neck malignancies and penile cancer patients only: Patients are scheduled for (primary) tumor (scar) removal with a subsequent sentinel node biopsy;
- For prostate cancer patients only: Patients with an increased risk of nodal metastases according to the Briganti nomogram (>10%);
- For prostate cancer patients only: Patients are scheduled for (robot-assisted) laparoscopic prostatectomy with a subsequent sentinel node biopsy procedure and selective lymph node dissection.

Exclusion criteria

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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-07-2014
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Opto-nuclear probe
Registration:	No

Ethics review

Approved WMO Date:	31-07-2014
Application type:	First submission
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	NL48676.031.14