Een prototype opto-nuclear probe voor gecombineerde radio- en fluroescentie geleide identificatie van de schildwachtklier(en)

No registrations found.

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

Summary

ID

NL-OMON27231

Source
Nationaal Trial Register

Brief title
-

Health condition

sentinel lymph node biopsy, prostate cancer, penile cancer, head and neck melanoma, oral cavity cancer

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL

Intervention

Outcome measures

Primary outcome

- 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 outcome

- 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.

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

Intraoperative fluorescence tracing of the sentinel node using the opto-nuclear probe is feasible.

Study design

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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.

Contacts

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Eligibility criteria

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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-08-2014
Application type:	First submission

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
NTR-new	NL4570
NTR-old	NTR4738
Other	NL48676.031.14 : N14ONP

Study results

Summary results

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