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

Gepubliceerd: 12-08-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27231

Bron
Nationaal Trial Register

Verkorte titel
-

Aandoening

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

Ondersteuning

Primaire sponsor: NKI-AVL
Overige ondersteuning: NKI-AVL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Department of Urology
The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
Plesmanlaan 121
H.G. Poel, van der
Amsterdam 1066 CX
The Netherlands
+31205129111

Wetenschappelijk

Department of Urology
The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
Plesmanlaan 121
H.G. Poel, van der
Amsterdam 1066 CX
The Netherlands
+31205129111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of iodine allergy;

- Hyperthyroid or thyroidal adenoma;

- Kidney insufficiency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2014
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4570
NTR-old	NTR4738
Ander register	NL48676.031.14 : N14ONP

Resultaten

Samenvatting resultaten

-