ICG-99mTc-nanocolloid vs. 99mTc-nanocolloid en een intraoperatieve injectie van ICG voor de schildwachtklierprocedure van prostaat kanker.

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

Intraoperative fluorescence imaging alone is sufficient to identify the sentinel nodes of the prostate as seen with preoperative radiocolloid-based sentinel node mapping

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

Samenvatting

ID

NL-OMON28336

Bron
Nationaal Trial Register

Aandoening

prostate cancer, sentinel lymph node

Ondersteuning

Primaire sponsor: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI/AVL)
Overige ondersteuning: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI/AVL), STW-VIDI Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of tumor positive lymph nodes.

Toelichting onderzoek

Achtergrond van het onderzoek

Recently fluorescent dyes such as indocyanine green (ICG) have been introduced into clinical practice for fluorescence-based sentinel node (SN) biopsy in a variety of malignancies, amongst others prostate cancer. A study by Jeschke et al. [Jeschke et al., Urology 2012] showed that intraoperative fluorescence imaging allowed SN and lymphatic duct visualization in prostate cancer. However, it did not allow for preoperative SN 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 with this tracer preoperative SN mapping was possible. In addition, intraoperatively, the fluorescence signature allowed for optical SN identification [van der Poel et al., Eur Urol 2012]. Logistical reasons, but also the fact that not every medical center has a highly skilled nuclear medicine department, lead to the suggestion that intraoperative fluorescence imaging can possibly replace the preoperatively radiocolloid-based method.

Doel van het onderzoek

Intraoperative fluorescence imaging alone is sufficient to identify the sentinel nodes of the prostate as seen with preoperative radiocolloid-based sentinel node mapping

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

On the morning of surgery patients will receive an transrectal-ultrasound guided intraprostatic or intratumoral injection with the hybrid tracer ICG-99mTc-nanocolloid (ARM 1) or 99mTc-nanocolloid (ARM 2). Thereafter, preoperative imaging will be performed: static lymphoscintigraphy (15min and 2hrs p.i.) and SPECT-CT imaging (2hrs p.i.). The nuclear medicine physician will evaluate the images and determine the number and location of the sentinel node(s).

Prior to the start of the operation, the patients in ARM 2 will receive an intraprostatic ICG injection. Then SN biopsy is performed. Intraoperatively, SNs will be initially pursued via

fluorescence imaging alone. After identification of all fluorescent SNs the urologist will evaluate the preoperative images (lymphoscintigraphy and SPECT/CT) to confirm removal of all preoperatively defined SNs. Thereafter, with the conventional gamma probe the area of resection will be checked for any remaining hot nodes. If there are any remaining SNs left in situ, these SNs will also be removed. After removal and documentation of all preoperatively defined SNs the subsequent extensive nodal dissection will be performed followed by the prostatectomy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- patients >18 years of age

- patients with histologically proven prostate cancer

- patients with an increased risk of nodal metastasis according to the MSKCC nomogram (>10%)

- scheduled for surgical (laparoscopic) prostatectomy including nodal dissection

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- patients with a history of iodine allergy

- patients with a hyperthyroid or thyroidal adenoma

- patients with kidney insufficiency

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	138
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	NL4565
NTR-old	NTR4733
Ander register	NL46580.031.13 : M13PSN

Resultaten

Samenvatting resultaten
van der Poel et al, Eur Urol 2012;
Jeschke et al., Urology 2012