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

No registrations found.

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

Summary

ID

NL-OMON28336

Source
Nationaal Trial Register

Health condition

prostate cancer, sentinel lymph node

Sponsors and support

Primary sponsor: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI/AVL)
Source(s) of monetary or material Support: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI/AVL), STW-VIDI Grant

Intervention

Outcome measures

Primary outcome

Number of tumor positive lymph nodes.

Secondary outcome

-

Study description

Background summary

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.

Study objective

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

Study design

-

Intervention

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.

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- patients with a history of iodine allergy

- patients with a hyperthyroid or thyroidal adenoma

- patients with kidney insufficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2014
Enrollment:	138
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	NL4565
NTR-old	NTR4733
Other	NL46580.031.13 : M13PSN

Study results

Summary results
van der Poel et al, Eur Urol 2012;
Jeschke et al., Urology 2012