Clinical evaluation of a prototype drop-in probe for (robot-assisted) laparoscopic sentinel node biopsy

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Primary objectives:- Determination of the sensitivity of the prototype drop-in probe for (robot-assisted) laparoscopic sentinel node(s) identification. Obtained results will be compared to those obtained using the conventional method(s);-...

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

Summary

ID

NL-OMON45762

Source
ToetsingOnline

Brief title
Evaluation of a drop-in probe for sentinel node biopsy

Condition

- Other condition

Synonym
prostate cancer sentinel node biopsy

Health condition

schildwachtklierprocedure bij prostaatkanker

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: NWO-STW-VIDI (STW BGT 11272) e,ERC-starting grant (2012-306890),onderdelen drop-in probes ter bruikleen gesteld door Eurorad

Intervention

Keyword: Drop-in probe, Laparoscopic surgery, Robotic surgery, Sentinel node biopsy

Outcome measures

Primary outcome

Intraoperative sentinel node detection using the drop-in probe.

Secondary outcome

-

Study description

Background summary

The sentinel node biopsy procedure is conventionally performed via a radioguided surgery approach: Upon the injection of a radiolabeled colloid preoperative imaging is performed to determine the number and location of the sentinel nodes. Intraoperatively then a laparoscopic gamma probe is used to guide the surgeon to the radioactive nodes. Prostate cancer sentinel node biopsy is generally performed via a (robot-assisted) laparoscopic approach for which then a laparoscopic gamma probe is used. However, because this probe has to be inserted through a trocar, its maneuverability is limited. Increasing the maneuverability of the gamma probe has the potential to further optimize the intraoperative sentinel node biopsy procedure. To this end, together with the company Eurorad we developed a prototype opto-nuclear probe that can be inserted through a trocar into the abdomen. Here it can be grabbed by a (robot-assisted) laparoscopic tool which possibly improves the maneuverability of the probe.

Study objective

Primary objectives:
- Determination of the sensitivity of the prototype drop-in probe for (robot-assisted) laparoscopic sentinel node(s) identification. Obtained results

will be compared to those obtained using the conventional method(s);
- Determination of the work-ability of the drop-in probe during (robot-assisted) laparoscopic sentinel node biopsy.

Secondary objectives:
- Evaluation of the ease of gripping prototype drop-in probe;
- Evaluation of the maneuverability of the prototype drop-in probe;
- Identification of (tumor-positive) sentinel node(s);

Study design

25 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 drop-in probe will be used for sentinel node identification. Findings of this prototype will be compared to that of the conventional standards (laparoscopic gamma probe and fluorescence camera).
- In the first 5 patients the drop-in probe will only be evaluated ex vivo * here sentinel node samples will be evaluated that were using the conventional approach.
- In the following 20 patients, the drop-in probe will be evaluated intraoperatively.

Intervention

On the morning of surgery, ICG-99mTc-nanocolloid will be injected intraprostatically. Lymphoscintigrams and SPECT/CT imaging will be performed to determine the number and location of the sentinel node(s).
Intraoperatively, after anesthetizing the patient, sentinel node biopsy will be performed. For this drop-in probe will be used. The sentinel node(s) will be localised using the conventional methods (laparoscopic gamma probe and fluorescence camera) and the drop-in probe (see note).
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 department of pathology department.

Note:
- In the first 5 patients the drop-in probe will only be evaluated ex vivo * here sentinel node samples will be evaluated that were excised using the conventional approach.
- In the following 10 patients the sentinel node(s) will be localised using the conventional methods, whereafter the drop-in probe will be evaluated intraoperatively.
- In the last 10 patients the sentinel node(s) will be localised using the drop-in probe, after which the localisation will be evaluated using the

conventional methods.

Study burden and risks

It will be evaluated if the findings of the drop-in probe are in line with the findings of the conventional methods. Of specific interest is the intraoperative sentinel node identification rate via gamma tracing. Also the clinical utility of the drop-in probe will be evaluated. Obtained results will be compared tot that of the gamma camera and the fluorescence camera (routinely used methods).

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

Risk-analysis revealed no direct risks for the intraoperative use of the drop-in gamma 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 prostate cancer;
- Patients are clinically N0M0 or NxMx;
- Patients are scheduled for (robot-assisted) laparoscopic procedure.

Exclusion criteria

- Patients with a history of iodine allergy;
- Patients with a hyperthyroid or thyroidal adenocarcinoma;
- Patients with 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):	01-10-2017
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	drop-in gamma probe
Registration:	No

Ethics review

Approved WMO Date:	14-09-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL57838.031.16