Pilot study on the use of fluorescence imaging of lymph nodes during laparoscopic pelvic sentinel node dissection for prostate cancer, using indocyanine green

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The potential use of intraoperative, ICG based sentinel node identification, fluorescence imaging of LN*s during lymphadenectomy for prostate cancer

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33246

Source ToetsingOnline

Brief title ICG sentinel node detection in prostate cancer

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym

prostate cancer, prostate carcinoma

Research involving

Human

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Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis **Source(s) of monetary or material Support:** Ministerie van OC&W,Nijbakker Morra stichting

Intervention

Keyword: prostate cancer, sentinel node, surgery

Outcome measures

Primary outcome

Feasibility of ICG fluorescence imaging in sentinel LN detection;

Secondary outcome

Matching ICG and gamma probe imaging

Study description

Background summary

Microscopic nodal metastases occur in 3-50% of men with presumed localized prostate cancer. In high risk patients, (laparoscopic) sentinel lymph node (SLN) dissection shows high reliability in staging of prostate cancer. Intraoperative detection of sentinel nodes, however, is currently performed using a gamma probe (radioisotope guided). The high tissue penetration makes it difficult to localize a radioactive lymph node, as the signal coming from the injection site will also be detected. A way to circumvent this is to measure under different angles and upgrade the gamma probe to a gamma camera. However, despite improvements in collimator technology, gamma camera detection always implies the use of a TV-monitor presenting the radionuclide image separate from the operative field image. In addition, it requires a dedicated camera operator that rotates the camera around the patient during surgery. Fluorescence imaging of SLN could potentially supplement this approach allowing for direct visual presentation of the SLN, using a laparoscopic camera (will be made available by Strorz). Here the low tissue penetration of the fluorescent dye limits the amount of background signal and thus improves the specificity. The fluorescent dye Indocyanine green (ICG) was shown to be useful for the intraoperative detection of sentinel nodes in a variety of tumors. A PTC (and ICG drug study) for the use of ICG in CRC-lymphatic imaging was also recently approved at the NKI-AVL. We, hypothesize that the use of ICG imaging could also enhance the

practicality of prostatic node dissection. In preclinical studies in mice with spontaneous prostate carcinoma*s (TRAMP-model) we have extensively tested this approach and compared it to the conventional radioisotope guided approach (both via intratumoral/intraprostatic injection). Within these preclinical models, the radioisotope NanoColl was used to plan the surgical procedure based on SPECT/CT and ICG proved to be a perfect addition to guide the surgical resection. Furthermore, a good correlation between fluorescent and *hot* nodes was observed. These preclinical studies also found a significant increase in detection sensitivity for ICG compared to the conventional blue dye (Patent blue): detection was possible up to 4h post ICG injection.

Study objective

The potential use of intraoperative, ICG based sentinel node identification, fluorescence imaging of LN*s during lymphadenectomy for prostate cancer

Study design

Non-randomised, open pilot study.

Intervention

Preoperative transrectal ultrasound guided intraprostatic injection of a cocktail of ICG and NanoColl

Study burden and risks

Other than intraoperative injection and tracking of ICG, this study will not result in any procedures different from the standard procedures. The ICG-injection will be given during the standard NanoColl sentinel node procedure of the prostate cancer. Operation time may be extended by 10-20 min. due to the imaging time. It may, however, be anticipated that the value of an improved and more adequate lymphadenectomy could have a major impact in the improvement of staging and postoperative outcome In rare cases (< 1/10.000) nausea, urticaria and anaphylactic reactions have been reported. Because of the proposed exclusion criteria, these numbers will be lower within this study.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Histology proven prostate cancer
- Increased risk of nodal metastases according to the MSKCC nomogram (>10%)
- Scheduled for surgical (laparoscopic) resection

Exclusion criteria

- History of allergy to iodides
- Hyperthyroid or autonomic thyroidal adenoma
- Kidney insufficiency

Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	20
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van

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 CCMO **ID** NL28143.031.09

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