Het gebruik van indocyanine groen voor de detectie van de schildwachtklier bij mannen met prostaatkanker met een hoog risico op klier metastasen. Wetenschappelijk onderzoek naar het verbeteren van de schildwachtklierprocedure voor prostaatkanker met behulp van fluorescentie

Gepubliceerd: 24-02-2014 Laatst bijgewerkt: 13-12-2022

The addition of fluorescence imaging to the standard radio-guided procedure improves intraoperative sentinel node detection.

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

Samenvatting

ID

NL-OMON20647

Bron
NTR

Verkorte titel
Optical sentinel node detection in prostate cancer

Aandoening

prostate cancer, sentinel node, lymph node, sentinel lymph node
prostaat kanker, schildwachtklier, lymfeklier

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
Plesmanlaan 121
1066CX Amsterdam
The Netherlands

Overige ondersteuning: - The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
- Intuitive Research Grant
- STW-VIDI grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Further validation of the sentinel node procedure for prostate cancer via an ultrasound-guided transrectal ICG-99mTc-nanocolloid.
- Improve the intraoperative detection of the true tumor draining (tumor positive) sentinel nodes by improved injection techniques.

Toelichting onderzoek

Achtergrond van het onderzoek

Presence of metastasis in the primary tumor draining lymph node(s) (so-called sentinel node(s)) in the pelvic region is considered a strong predicator of treatment failure in patients with prostate cancer. Postoperative histopathological examination of tissue samples obtained during surgery is considered the gold standard to assess the metastatic spread. To obtain these samples, extensive dissection of the lymphatic tissue is required, a procedure that can lead to postoperative complications such as lymphocele, injuries to the obturator nerve and/or the ureter, and lymphedema of the lower extremity. Moreover, despite an increase in resected lymph nodes, early sentinel lode studies have indicated locations of primary landing sites outside the extended field in 5-10% of cases.
Surigical pelvic lymphadenectomy can be improved with better surgical guidance along the (tumor draining) lymphatic ducts towards the (sentinel) lymph nodes. Ideally, an intraoperative imaging approach enables the surgeon to visualize and excise those sentinel nodes accurately, which may shorn overall procedure time and decrease complication levels. Innovations in lymph node mapping have come mainly from the melanoma and breast cancer field. At present, lymph node mapping in e.g.. the breast is performed with a combination of preoperative 99m-Tc-labeled nano colloid injection and intraoperative injection of blue dyes

(e.g. patent blue) for visible guidance.
Preoperative lymphoscintigraphy, using 99m-Tc-labeled nanocolloidal particles, has also demonstrated its use in imaging of the sentinel nodes in the prostate. The intraoperative translation of the radio colloid procedure requires the use of a gamma probe or camera to monitor the transit of the colloid from the injection site to the sentinel node(s). Unfortunately, the applicability of radionuclide-based intraoperative detection remains challenging. Ideally, an extra visual aid, e.g. blue dyes, can help guide the surgeon. However, the dynamics of the conventional blue dye limit its use in prostate cancer.
Recently, several promising new trials have been published for breast, prsotate and gastrointestinal cancer using the near-infrared fluorescent dye indocyanine green (ICG) for intraoperative fluorescence detection of the lymph nodes. in a feasibility study (in breast cancer), the FDA suggested that a cocktail injection of fluorescent and radioactive agents would be preferable over multiple singe injections. In the preclinical setting we have fully optimized this approach in a spontaneous mouse model of prostate cancer.
In our initial feasibility study we showed the use of the hybrid tracer ICG-99mTc-nanocolloid for sentinel node mapping during laparoscopic sentinel node dissection for prostate cancer. Here we showed that with the hybrid tracer we were able to facilitate and optimized dissection of the sentinel nodes during RALP procedures. ICG-99mTc-nanocolloid allowed preoperative surgical planning and intraoperative optical detection of the sentinel nodes. Furthermore it was found that especially when sentinel nodes were located close to the injection site, fluorescence imaging was useful as gamma probe detection was hindered due to the background signal coming from the injection site. In addition to this, the fluorescence signal (which can be detected >3 months after injection in the formalin-fixed paraffin-embedded tissue samples) allowed us to study the influence of the injection site on the observed lymphatic drainage pattern. Fluorescence imaging of these samples suggested that the location where the tracer is injected is of influence on the observed lymphatic drainage pattern.

Doel van het onderzoek

The addition of fluorescence imaging to the standard radio-guided procedure improves intraoperative sentinel node detection.

Onderzoeksopzet

Day of surgery.

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. 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 images are presented to the urologist. Intraoperatively, sentinel nodes are identified via fluorescence imaging (and gamma tracing).

Contactpersonen

Publiek

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Wetenschappelijk

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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:	28-05-2013
Aantal proefpersonen:	112
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-02-2014
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	NL4306
NTR-old	NTR4451
Ander register	NL41285.031.12 : N12IGP

Resultaten

Samenvatting resultaten
- van der Poel et al., Eur Urol 2011.
- Buckle et al., JNM 2012.