Bladder cancer sentinel node mapping using ICG-99mTc-nanocolloid

Gepubliceerd: 18-05-2015 Laatst bijgewerkt: 13-12-2022

Sentinel node mapping for bladder cancer is possible using the hybrid tracer ICG-99mTc-nanocolloid

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

Samenvatting

ID

NL-OMON21640

Bron
NTR

Verkorte titel
Hybrid tracer for bladder cancer sentinel node biopsy

Aandoening

Bladder cancer; Bladder carcinoma;

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Plesmanlaan 121, 1066 CX, Amsterdam, the Netherlands
Overige ondersteuning: The Netherlands Cancer Institute, Amsterdam, the Netherlands, Division HOD

NWO-STW-VIDI (Grant No. STW BGT11272)

ERC-starting Grant (Grant No. 2012-306890)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Evaluate the accuracy of the sentinel node biopsy procedure for nodal staging in patients with non-metastatic (cN0M0) muscle-invasive bladder cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

Radical cystectomy combined with an extended pelvic lymph node dissection is considered the gold standard for staging in non-metastatic muscle-invasive bladder cancer. The sentinel node procedure is an alternative method to locally stage bladder cancer. In this study we aim to evaluate the sentinel node procedure in bladder cancer patients who are scheduled for radical cystectomy and extended pelvic lymph node dissection.

Doel van het onderzoek

Sentinel node mapping for bladder cancer is possible using the hybrid tracer ICG-99mTc-nanocolloid

Onderzoeksopzet

Injection (t=0); Preoperative imaging (t=15 min, and t=2 hours); Intraoperative imaging (t=>3hours)

Onderzoeksproduct en/of interventie

On the day before surgery (approximately 18 hours) patients will receive 4-6 transurethral injections with a total of 2mL hybrid tracer (240MBq) around the tumor (in case of a solitary lesion) or divided over the bladder (in case of multiple tumors). In both cases the hybrid tracer is injected into the detrusor muscle of the bladder under cystoscopy guidance using an endoscopic needle.

After the injection lymphoscintigraphy will be performed at 15 min and 2 hours, followed by SPECT/CT imaging at 2 hours.

Intraoperatively sentinel nodes will be identified via combined radio- and fluorescence guidance. For radioguidance, a (laparoscopic) gamma probe will be used. Fluorescence imaging during the operation will be performed using a fluorescence camera for open surgery

or for laparoscopic surgery. Additionally, during robot-assisted procedures, the da Vinci SI integrated fluorescence camera (Firefly) will be used. The declipseSPECT navigation system will be used to locate the sentinel nodes intraoperatively.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients >18 years;

- Histopathologically proven bladder cancer;

- Patients are cN0M0;

- Patients scheduled for radical cystectomy with or without neo-adjuvant chemotherapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Preoperatively known distant metastases (M1);

- Clinically tumor-positive nodes;

- Patients scheduled for brachytherapy of the bladder;

- Previous radiation therapy of the pelvis;

- Previous pelvic surgery for other reasons such as urologic and gynecologic malignancies (exception: trans-urethral operations like e.g. transurethral bladder resection).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2015
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	NL5088
NTR-old	NTR5220
Ander register	: M14HSN

Resultaten