Sentinel node biopsy for bladder cancer using the hybrid tracer

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Evaluation of the accuracy of the sentinel node procedure in bladder cancer patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON41181

Source
ToetsingOnline

Brief title
Hybrid sentinel node biopsy for bladder cancer

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Bladder cancer, Bladder carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO-STW-VIDI (Grant No. STW BGT11272)

Intervention

Keyword: Bladder cancer, hybride tracer, Sentinel node

Outcome measures

Primary outcome

To evaluate the accuracy of the SN biopsy for nodal staging in patients with

muscle invasive bladder cancer.

Secondary outcome

• Evaluation of intraoperative fluorescence detection of the SNs;

• Feasibility of intraoperative SPECT/CT-based navigation using the

declipseSPECT system;

• Feasibility of freehand SPECT-based navigation to the SN using the

declipseSPECT navigation system.

Study description

Background summary

Sentinel node (SN) biopsy for staging was initially introduced in breast cancer, melanoma patients and penile cancer. A SN is defined as a first primary draining LN from the tumor (organ), without any interception of another LN in the lymph tract. Multiple SNs can be present in one patient. The location of the SN can be depicted on lymphoscintigraphy and SPECT/CT following an injection of a radiocolloid (99mTc-nanocolloid) that is then transported through the lymphatic system into the SN.
Provided that the spread of tumor cells is in a orderly fashion, compared to the ePLND, SN biopsy can be restricted to resection of the SNs only, and as such is able to determine the regionally lymphatic status in clinically tumor negative patients in a minimally invasive manner. For bladder cancer different authors described the SN procedure using different tracers . The results of these studies show that the SN procedure is accurate and is able to locate the SNs outside the ePLND.
The purpose of this trial is to evaluate the accuracy of the SN biopsy in localization of tumor positive (sentinel) lymph nodes. For this purpose we will use the hybrid tracer ICG-99mTc-nanocolloid. This tracer is both radioactive and fluorescent allowing preoperative lymphoscintigraphy and single photon emission computed tomography (SPECT) combined with computed tomography (CT) (SPECT/CT) imaging for preoperative and intraoperative localization of the SN

with a radioactive signal and optically with fluorescence.

Study objective

Evaluation of the accuracy of the sentinel node procedure in bladder cancer patients.

Study design

Prospective, interventional study

Intervention

On the day before surgery (approximately 18hours) patients will receive 4-6 transurethral injections with a total of 2mL hybrid tracer ICG-99mTc-nanocolloid (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 2hours, 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.

Study burden and risks

The total dose of radioactivity lies within the limits that are indicated by the Gezondheidsraad, in the *Normen voor de toediening van radioactieve stoffen aan vrijwilligers*.
Rarely, nausea, urticaria and anaphylactic reactions (<1/10,000) have been reported after intravenous injection of ICG. Because of the proposed exclusion criteria and the intravesical injection, these numbers may be assumed to be lower within this study.
The patients remain at risk for all complications related to an extended pelvic lymph node dissection such as: lymphocele, hematoma and ureteral lesions.

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 with clinically localized bladder cancer
Patients with proven histological-pathological bladder cancer
Patients scheduled for brachytherapy or radical cystectomy with or without neo-adjuvant chemotherapy
Patients with cN0 lymph node status

Exclusion criteria

Patients with preoperatively known distant metastases (M1);
Patients with clinically tumor positive nodes;
Previous radiation therapy of the pelvis;

Previous pelvic lymphadenectomy for other reasons such as urologic and gynecologic malignancies

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-10-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-11-2014
Application type:	First submission
Review commission:	METC NedMec

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	NL48901.031.14