

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21640

### Source

Nationaal Trial Register

### Brief title

Hybrid tracer for bladder cancer sentinel node biopsy

### Health condition

Bladder cancer; Bladder carcinoma;

## Sponsors and support

**Primary sponsor:** The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Plesmanlaan 121, 1066 CX, Amsterdam, the Netherlands

**Source(s) of monetary or material Support:** The Netherlands Cancer Institute, Amsterdam, the Netherlands, Division HOD

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

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

## Intervention

## Outcome measures

### Primary outcome

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

## **Secondary outcome**

1. Evaluation of the feasibility of sentinel node mapping in bladder cancer patients using the hybrid tracer (ICG-99mTc-nanocolloid);
2. Evaluation of intraoperative fluorescence detection of the SNs via fluorescence imaging;
3. Evaluation of the feasibility of sentinel node localization via intraoperative (SPECT/CT-based and freehandSPECT).

## **Study description**

### **Background summary**

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.

### **Study objective**

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

### **Study design**

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

### **Intervention**

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.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- Patients >18 years;
- Histopathologically proven bladder cancer;
- Patients are cN0M0;
- Patients scheduled for radical cystectomy with or without neo-adjuvant chemotherapy.

### **Exclusion criteria**

- 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).

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	30
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	18-05-2015
Application type:	First submission

## 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
NTR-new	NL5088
NTR-old	NTR5220
Other	: M14HSN

**Study results**