# Lymphatic drainage of the urinary bladder in bladder cancer patients scheduled for cystectomy

Submission date Recruitment status Prospectively registered 20/01/2009 No longer recruiting [ ] Protocol Statistical analysis plan Overall study status Registration date 10/02/2009 Completed [X] Results [ ] Individual participant data Last Edited Condition category 14/11/2013 Cancer

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Beat Roth

#### Contact details

Urologische Klinik Inselspital Bern Switzerland 3010

## Additional identifiers

Protocol serial number 31/07

# Study information

Scientific Title

A multimodality technique of single photon emission computed tomography fused with computed tomography (SPECT-CT) and intraoperative verification by gamma probe used to map the primary lymphatic landing sites of the urinary bladder wall in patients scheduled for cystectomy

#### Study objectives

Surgical excision and histological examination of the pelvic lymph nodes (LNs) provides the most accurate staging regarding pelvic lymph node status in patients undergoing radical cystectomy for invasive urinary bladder cancer. Whilst the optimal field of lymphadenectomy is still debated, there is growing evidence that extended pelvic lymph node dissection (PLND) in patients with bladder cancer may confer a survival benefit for both node-positive and node-negative patients. The purpose of this study was to prospectively determine the anatomical location of the draining LNs after injection with a radioactive tracer in the lateral, non tumour bearing bladder wall and to evaluate the implications for the extent of PLND in strictly unilateral bladder cancer.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Committee of Bern, approved in February 2007 (ref: 31/07)

#### Study design

Interventional prospective single-arm single-centre study

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Lymphatic drainage of urinary bladder in bladder cancer patients

#### **Interventions**

Preoperative flexible cystoscopy guided injection of technetium into the bladder wall in patients with bladder cancer scheduled for cystectomy and extended PLND. Thereafter, all patients undergo preoperative SPECT-CT to detect Tc 99m positive nodes. Intraoperative gamma probe detection at the time of PLND. Removal of Tc 99m positive nodes separately. Backup extended PLND to detect possibly missed Tc 99m positive nodes.

#### Intervention Type

Other

#### **Phase**

Not Applicable

## Primary outcome(s)

Lymphatic drainage: regions of the different bladder sites

#### Key secondary outcome(s))

## Reduction of lymph node dissection field

## Completion date

31/12/2009

# **Eligibility**

## Key inclusion criteria

- 1. Both males and females, age range: 18-90 years
- 2. Invasive urinary bladder cancer
- 3. Informed consent

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

90 years

#### Sex

All

## Key exclusion criteria

- 1. T4 bladder cancer
- 2. Lymph node positive
- 3. Metastases seen on CT scan
- 4. Pregnancy
- 5. Previous operations to the pelvis

#### Date of first enrolment

01/03/2007

#### Date of final enrolment

31/12/2009

## Locations

#### Countries of recruitment

Switzerland

Study participating centre Urologische Klinik Bern

Switzerland 3010

# Sponsor information

## Organisation

Inselspital, University Hospital Berne (Switzerland)

#### **ROR**

https://ror.org/01q9sj412

# Funder(s)

## Funder type

Hospital/treatment centre

#### **Funder Name**

Inselspital, University Hospital Berne, Department of Urology (Switzerland)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created Date a	dded Peer reviewed?	Patient-facing?
Results article	results	01/02/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/	/2025 No	Yes