

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

Submission date 20/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Single-centre

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Lymphatic drainage: regions of the different bladder sites

Secondary outcome measures

Reduction of lymph node dissection field

Overall study start date

01/03/2007

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

60

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)

Sponsor details

c/o Dr Beat Roth

Urologische Universitätsklinik

Inselspital

Bern

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3010

Sponsor type

Hospital/treatment centre

Website

<http://www.insel.ch/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No