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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No