

Does the closure of the dorsal peritoneal layer after cystectomy and extended pelvic lymphadenectomy have a significant beneficial impact on early post-operative recovery and complications?

Submission date 26/05/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/07/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 09/07/2009	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

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
51/09

Study information

Scientific Title

Closure of the dorsal peritoneal layer after pelvic lymphadenectomy (PLND) and its impact on early post-operative recovery and complications: a randomised, single blinded, single centre study

Study objectives

A delay of intestinal transit, prolonged post-operative pain, a delay in mobilisation and therefore increased post-operative complications such as pneumonia, deep venous thrombosis and pulmonary embolism are frequently seen after cystectomy and pelvic lymphadenectomy (PLND). This may be due to adhesions of small bowel and iliac vessels after PLND and cystectomy.

Our hypothesis is that closing the dorsal peritoneal layer over the iliac vessels bilaterally after cystectomy and PLND has a beneficial impact on gastrointestinal recovery, post-operative pain management and complications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission des Kantons Bern gave approval on the 25th May 2009

Primary study design

Interventional

Study design

Randomised single blinded single centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prolonged post-operative pain

Interventions

Patients will be randomised to one of two groups:

1. Without closure of the dorsal peritoneal layer after PLND (as performed traditionally)
2. With closure of the dorsal peritoneal layer bilaterally over the iliac vessels; performed with a running suture on each side

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Complications (according to the Dondo/Clavien Classification System), measured post-operatively on days 1, 3, 7, 10, 14, and at 3, 6, 12 and 24 months.

Key secondary outcome(s)

1. Pain: according to the VAS (Visual Analogue Scale)
2. Bowel function/intestinal recovery: passage of stool, flatulence, nausea, vomiting

Measured post-operatively on days 1, 3, 7, 10, 14, and at 3, 6, 12 and 24 months.

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

1. A consecutive series of 200 patients scheduled for cystectomy and PLND for malignancy of the urinary bladder
2. Aged greater than 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Aged less than 18 years
2. Pregnancy
3. No informed consent available
4. Previous surgery of the pelvis with lymphadenectomy
5. Previous radiotherapy to the pelvis
6. Previous chemotherapy due to malignancy of pelvic organs

Date of first enrolment

01/01/2009

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

Switzerland

Study participating centre
Department of Urology
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 (Switzerland) - Department of Urology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration