

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/07/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised single blinded single centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

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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 (Switzerland) - Department of Urology

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