

Effects of thoracic epidural administered drugs on lower urinary tract function: a randomized controlled study

Submission date 17/03/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/04/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/05/2017	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Urinary retention is the inability to empty the bladder completely. It is one of the most common complications after surgery and anesthesia. Urination depends on coordinated actions between the bladder muscle and the urethral sphincter muscles. Under the influence of epidural analgesia (pain catheter), patients may not feel the sensation of bladder filling, which can result in urinary retention and bladder damage. Epidural analgesia (pain relief) is provided with local anesthetics that block pain sensation. The anaesthetic drug bupivacaine blocks bladder muscle activity (a motor block), resulting in residual urine remaining in the bladder after urination, which requires monitoring or drainage. The epidural administration of a relatively new anaesthetic drug ropivacaine during labour has resulted in fewer motor blocks. The aim of this study is to find out whether using ropivacaine results in less significant changes in lower urinary tract function than bupivacaine, in patients undergoing renal (kidney) surgery.

Who can participate?

Patients undergoing renal surgery with normal bladder function.

What does the study involve?

Participants are randomly allocated to receive either ropivacaine or bupivacaine during their surgery. Participants also undergo tests to assess their bladder function before and after the surgery.

What are the possible benefits and risks of participating?

This study will improve our knowledge of bladder function during epidural analgesia. The immediate benefit to the participants is that in case of normal bladder function no bladder catheter is needed, which reduces the risk of a urinary tract infection, a frequent complication after surgery. Due to the additional bladder tests in this study, there is a slightly increased risk for urinary tract infections. However, all the patients undergoing the bladder tests receive antibiotics as recommended by the guidelines.

Where is the study run from?

Departments of Anaesthesiology and Urology of the University Hospital Bern (Switzerland)

When is the study starting and how long is it expected to run for?

April 2015 to May 2017

Who is funding the study?

University Hospital Inselspital (Switzerland)

Who is the main contact?

PD Dr. med. Patrick Wüthrich

patrick.wuethrich@insel.ch

Contact information

Type(s)

Scientific

Contact name

Dr Patrick Wuethrich

Contact details

Department of Anaesthesiology and Pain Therapy

University Hospital Bern Inselspital Bern

Berne

Switzerland

3010

Additional identifiers

Protocol serial number

SNCTP000001322

Study information

Scientific Title

Effects of thoracic epidural administered ropivacaine versus bupivacaine on lower urinary tract function: a randomized controlled study

Study objectives

To evaluate the epidural administration of ropivacaine on lower urinary tract function. The primary hypothesis is that thoracic epidural analgesia (TEA) with the local anesthetics ropivacaine leads to less significant changes in lower urinary tract function than bupivacaine as a control group, in patients undergoing lumbotomy incision for renal surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Primary study design

Interventional

Study design

Randomized parallel-group single-centre interventional assessor-blind trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Kidney surgery

Interventions

All patients will receive a TEA placed at the insertion site interspace T7-8 or T8-9. Segmental blockade will be achieved using the solutions according to the randomisation.

Group 1: Ropivacaine 2 mg/ml (ROPIVACAIN Sintetica 2 mg/ml TM, Sintetica-Bioren, Couvet, Schweiz)

Group 2: Bupivacaine 1.25 mg/ml (BUPIVACAIN Sintetica 0.125 % TM (Bupivacain 1.25 mg/ml – Fentanyl 2 µg/ml), Sintetica-Bioren, Couvet, Schweiz)

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Ropivacaine , Bupivacain

Primary outcome(s)

Post-void residual urine volume (in ml) during thoracic epidural analgesia, measured before surgery (baseline) and on postoperative two or three depending of the patient's mobility.

Key secondary outcome(s)

Urodynamic parameters of the storage phase and micturition (e.g. bladder volume at first desire to void, maximum cystometric capacity, bladder compliance, urethral pressure profile, detrusor activity, maximum detrusor pressure, detrusor pressure at maximum flow rate, maximum flow rate, pelvic floor electromyographic activity, incidence of urinary retention). Primary and secondary outcomes will be measured before surgery (baseline) and on postoperative two or three depending of the patient's mobility. The method used will an urodynamic investigation and secondly assessment of the parameters of the voiding phase. Urodynamic investigations will be performed according to good urodynamic practice. After placement of a 6 French transurethral dual channel catheter and a 14 French rectal balloon catheter (Gaeltec, Dunvegan, Scotland), the bladder will be filled at a rate of 25 to 50 ml/min with Ringer's lactate solution at room temperature. Parameters of both the storage phase (maximum cystometric capacity, bladder compliance) and voiding phase (detrusor pressure at maximum flow rate [PdetQmax], maximum flow rate [Qmax] and PVR) will be recorded. A TRITONTM multichannel urodynamic

system will be used for all measurements (Laborie Medical Technologies Corp., Toronto, Canada). All methods, definitions and units will be in accordance with the standards recommended by the International Continence Society.

Completion date

15/05/2017

Eligibility

Key inclusion criteria

1. Written informed consent
2. Kidney surgery
3. Thoracic epidural analgesia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Contraindications to epidural analgesia or refusal
2. Preoperative PVR > 100 ml
3. International Prostate Symptom Score (IPSS) > 7
4. Pregnancy (pregnancy test in all women who are not in menopause, exclusion for surgery per se)

Date of first enrolment

17/04/2015

Date of final enrolment

12/05/2017

Locations

Countries of recruitment

Switzerland

Study participating centre**Urology Department**

University Hospital Bern Inselspital Bern
Bern

Switzerland
3010

Sponsor information

Organisation

Department of Anaesthesiology, University Hospital Inselspital

ROR

<https://ror.org/01q9sj412>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Inselspital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from PD Dr. med. Patrick Wüthrich (patrick.wuethrich@insel.ch).

IPD sharing plan summary

Available on request