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

Submission date	**Recruitment status**	[X] Prospectively registered
17/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/04/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2017	Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
Kantonale Ethikkommission Bern (KEK BE) (Ethics Committee of Canton Berne), 10/03/2015, ref: 390/14

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

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 ™, Sintetica-Bioren, Couvet, Schweiz)
Group 2: Bupivicaine 1.25 mg/ml (BUPIVACAIN Sintetica 0.125 % ™ (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 measure
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.

Secondary outcome measures
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 TRITON™ 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.

Overall study start date
01/04/2015

Completion date
15/05/2017

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
42

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

Sponsor details
Freiburgstrasse
Berne
Switzerland
3010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Inselspital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/05/2018

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