

Ultrasound guided spermatic cord block for scrotal surgery

Submission date 10/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/02/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
N/A

Study information

Scientific Title

Ultrasound guided spermatic cord block for scrotal surgery: a feasibility pilot study

Study objectives

Blindly performed spermatic cord blockade are known to be difficult, painful and has potential risk (intravasal injection of local anaesthesia, perforation of vessels and perforation of the deferent duct). The aim of this study is to test the feasibility of ultrasound guided spermatic cord blockade.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethics committee (Kantonale Ethikkommission KEK) approved on the 10th November 2008 (ref: 167/08)

Study design

Non-randomised, non-controlled feasibility pilot study

Primary study design

Interventional

Secondary study design

Non 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

Regional anaesthesia

Interventions

After antiseptic cleaning of the external genitalia, the spermatic cord is grasped gently between the left thumb and index finger. Using a 2 cm pediatric ultrasound probe the spermatic cord is identified by searching the testicular artery and the deferent duct. Using a 22 G Microlance needle the local anaesthesia (10 ml) is slowly injected around the ductus deferens avoiding vessel perforation.

Patients will then receive either a subcapsular orchiectomy or a vaso-vasostomy.

As of 17/06/2010 the above anticipated end date of this trial has been amended to the actual end date. The initial anticipated end date at the time of registration was 31/12/2009.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Success rate of the blockade defined as surgery without any substitution (analgesics, conversion to general anaesthesia).

Secondary outcome measures

1. Visual Analogue Scale (VAS) (0 - 10) during blockade and every 30 minutes after beginning of surgery
2. Volume of local anaesthesia for blockade
3. Duration of blockade: defined as point of time of the first demand of analgesics after surgery
4. Patient satisfaction (scale 0 - 5) in general 1 week after surgery

Overall study start date

01/01/2009

Completion date

01/03/2010

Eligibility

Key inclusion criteria

Electively planned patients (male or female aged at least 16 years - no upper age limit), for subcapsular orchiectomy or vaso-vasostomy.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Refusal of regional anaesthesia
2. Patients with anticoagulation
3. Anamnesis of haemorrhagic diathesis
4. Adipositas (Body Mass Index [BMI] greater than 40)

Date of first enrolment

01/01/2009

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital Berne

Bern

Switzerland

3010

Sponsor information

Organisation

University of Bern (Switzerland)

Sponsor details

Department of Anaesthesia and Pain Therapy

Inselspital Bern

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Sponsor type

University/education

Website

<http://www.unibe.ch/eng/>

ROR

<https://ror.org/02k7v4d05>

Funder(s)

Funder type

University/education

Funder Name

University of Berne (Switzerland) - Scientific fund of the Department of Anaesthesia and Pain Therapy

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2011		Yes	No