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Ultrasound guided spermatic cord block for scrotal surgery

Submission date	Recruitment status	[_] Prospectively registered
10/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/06/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/02/2011	Surgery	

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 pedriatic 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
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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