ISRCTN95628829 https://doi.org/10.1186/ISRCTN95628829

Dosing of hyperbaric prilocaine 2% for perianal surgery in an ambulatory setting

Submission date	Recruitment status	[ ] Prospectively registered
11/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/06/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/06/2011	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marc D Schmittner

Contact details
Universitätmedizin Mannheim
Klinik für Anästhesiologie und Operative Intensivmedizin
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of 0.5ml vs. 1.0ml vs. 1.5ml hyperbaric prilocaine 2% for spinal saddle block in patients undergoing perianal surgery in an ambulatory setting

Study objectives
In 2010 hyperbaric prilocaine 2% was introduced on the German market. There is no evidence based data about dosing of hyperbaric prilocaine 2% for perianal surgery. In this trial we compare the expansion of the saddle block according to three dosages of hyperbaric prilocaine 2%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee II, Faculty of Medicine, Ruprecht Karl University of Heidelberg (Medizinische Ethikkommission II: MEdizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg), approved on 21st September 2010 (ref: AZ.: 2010-303N-MA)

Study design
Randomised controlled single-centre trial

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
Colorectal diseases

Interventions
Participants are randomised (1:1:1) to a dose of either 0.5ml or 1.0ml or 1.5ml of hyperbaric prilocaine 2%. The expansion of anaesthesia is tested with a toothpick and an ice-filled plastic tube.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prilocaine 2%

Primary outcome measure
Expansion of anaesthesia tested with a toothpick and an ice-filled plastic tube. The expansion of anaesthesia is tested at two points of time:
1. After positioning of the patient for operation
2. Directly after the procedure has ended

Secondary outcome measures
1. Practicability
2. Postoperative analgetic consumption
3. Duration of stay in hospital

Overall study start date
07/12/2010

Completion date
07/07/2011

Eligibility

Key inclusion criteria
1. Patients (male/female) undergoing minor perianal surgery
2. Age: 18-80 years
3. American Society of Anesthesiologists (ASA) physical status I-III
4. No contraindications for spinal anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Contraindications for spinal anaesthesia
2. Allergy to diclofenac

Date of first enrolment
07/12/2010

Date of final enrolment
07/07/2011

Locations

Countries of recruitment
Germany

Study participating centre
Universitätmedizin Mannheim
Mannheim
Germany
68167

Sponsor information

Organisation
University Medical Centre Mannheim (Universitätsmedizin Mannheim) (Germany)

Sponsor details
Klinik für Anästhesiology und Operative Intensivmedizin
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167

Sponsor type
University/education

ROR
https://ror.org/05sxbyd35

Funder(s)

Funder type
University/education

Funder Name

University Medical Centre Mannheim (Universitätsmedizin Mannheim) (Germany) - Department of Anaesthesiology and Intensive Care Medicine (Klinik für Anästhesiologie und Operative Intensivmedizin)

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