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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Practicability
2. Postoperative analgetic consumption
3. Duration of stay in hospital

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration