

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

Submission date 11/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2011	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes