

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

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

## 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