# Spinal anaesthesia or general anaesthesia for anorectal surgery

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
03/12/2007		☐ Protocol		
Registration date 20/03/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/01/2010	Surgery			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Thomas Luecke** 

#### Contact details

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## Additional identifiers

Protocol serial number N/A

# Study information

#### Scientific Title

Comparison of spinal anaesthesia with 1.0 mL hyperbaric bupivacaine 0.5% and total intravenous anaesthesia for minor anorectal surgery

### Study objectives

Minor anorectal surgery can be performed with several anaesthesia techniques. Due to multiple irrational fears, many patients deny a spinal anaesthesia and prefer a general anaesthesia. In this study we evaluate the practicability, patients' acceptability and analgetic consumption for both anaesthesia techniques in patients undergoing minor anorectal surgery.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local medical ethics committee (Medizinische Ethikkommission II Anschrift: Medizinische Ethik-Kommission II) on the 24th May 2007 (ref: 2007-085N-MA).

#### Study design

Single-centre, randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

**Treatment** 

#### Health condition(s) or problem(s) studied

Minor anorectal surgery

#### **Interventions**

Patients with anorectal surgery are 1:1 randomised to either a spinal anaesthesia or a general anaesthesia. All patients received either:

- 1. A spinal anaesthesia with 1.0 mL hyperbaric bupivacaine 0.5% or
- 2. A total intravenous anaesthesia with:
- 2.1. 0.2 mg fentanyl and 2 mg propofol 1% per kg body weight for induction
- 2.2. Propofol 1% in a perfusion pump for the duration of anaesthesia, dosage depending on the demands of the patient
- 2.3. A laryngeal mask (size depending on the body weight of the patient)

#### Intervention Type

Drug

#### Phase

**Not Specified** 

# Drug/device/biological/vaccine name(s)

Fentanyl, propofol, bupivacaine

#### Primary outcome(s)

Recovery room time, measured on day of surgery.

# Key secondary outcome(s))

Consumption of analgetics in the first 24 hours, measured 48 hours after surgery.

## Completion date

# **Eligibility**

#### Key inclusion criteria

- 1. Patients (male/female) with minor anorectal surgery
- 2. Operation in jack knife position
- 3. Age: 18 75 years
- 4. American Society of Anaesthesiologists (ASA) grade I II
- 5. No contra-indication against spinal anaesthesia or general anaesthesia

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Contra-indications against spinal anaesthesia or general anaesthesia
- 2. Operations in prone position
- 3. Allergy against diclofenac

#### Date of first enrolment

01/09/2007

#### Date of final enrolment

01/02/2008

# Locations

#### Countries of recruitment

Germany

# Study participating centre

Clinic of Anaesthesiology and Critical Care Medicine

Mannheim Germany

68167

# Sponsor information

## Organisation

University Hospital Mannheim (Germany)

#### **ROR**

https://ror.org/05sxbyd35

# Funder(s)

# Funder type

Other

#### **Funder Name**

Investigator initiated and funded (Germany)

# **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?
Results article	results	01/01/2010		Yes	No