

Spinal anaesthesia or general anaesthesia for anorectal surgery

Submission date 03/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

Recovery room time, measured on day of surgery.

Secondary outcome measures

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

Overall study start date

01/09/2007

Completion date

01/02/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

Clinic of Anaesthesiology and Critical Care Medicine

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05sxbyd35>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No