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Spinal anaesthesia or general anaesthesia for anorectal surgery

Submission date	Recruitment status	[_] Prospectively registered
03/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2008	Completed	[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

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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
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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