ISRCTN28052769 https://doi.org/10.1186/ISRCTN28052769

Spinal anaesthesia or general anaesthesia for surgery of pilonidal fistula

Submission date 23/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/05/2011	**Overall study status** Completed	
Last Edited 17/05/2011	**Condition category** Surgery	

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 spinal anaesthesia with 1.5 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 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.

Further reading:
2010 results of related trial [ISRCTN41981381] in http://www.ncbi.nlm.nih.gov/pubmed/19937984

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 18th March 2010 (ref: 2010-215N-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 1.5 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. An orotracheal intubation

Intervention Type
Procedure/Surgery

Phase
Not Applicable

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
30/06/2011

Eligibility

Key inclusion criteria
1. Patients (male/female) with minor anorectal surgery
2. Operation in prone position
3. Age: 18 - 80 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. Allergy against diclofenac

Date of first enrolment
01/07/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Germany

Study participating centre
Clinic of Anaesthesiology and Critical Care Medicine
Mannheim
Germany
68167

Sponsor information

Organisation
University Hospital Mannheim (Gernany)

ROR
https://ror.org/05sxbyd35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Mannheim (Gernany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration