

Spinal anaesthesia or general anaesthesia for surgery of pilonidal fistula

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| Submission date 23/08/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/05/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 17/05/2011 | Condition category Surgery | <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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient 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 1.5 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 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

01/07/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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 (Germany)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Mannheim (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