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Comparison of prilocaine and mepivacaine for perianal surgery in an outpatient setting

Submission date
15/05/2012

Recruitment status
No longer recruiting

Registration date
25/07/2012

Overall study status
Completed

Last Edited
25/07/2012

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Minor colorectal diseases such as condyloma (infection of the genitals), fissures or haemorrhoids are very common amongst the adult population. If surgical treatment is necessary, procedures are usually performed in an ambulatory setting (outpatient surgery/day care). Spinal anaesthesia with small amounts of hyperbaric local anaesthetics seems to be more efficient than other anaesthesia techniques. In July 2010, prilocaine 2%, a new hyperbaric local anaesthetic, was introduced to the market. Compared to formerly used mepivacaine, prilocaine seems to have a shorter time of drug-action and a lower rate of adverse side effects. Therefore prilocaine 2% may be the preferred anaesthetic for perianal outpatient surgery. The aim of this study is to compare prilocaine and mepivacaine regarding adverse side effects, amount of additional analgesics needed as well as the duration of patients stay in day care.

Who can participate?
Every patient suffering from minor colorectal diseases aged 18 to 80 can take part in this study, except for patients who have the following: contraindications against spinal anaesthesia, not eligible for day surgery, allergies against local anaesthetics or drugs used for postoperative analgesia.

What does the study involve?
Participants are randomly allocated to either 0.5ml of hyperbaric prilocaine 2% or 0.5ml of hyperbaric mepivacaine 4%. The expansion of sensory and motor blocks are tested. After the procedure, the period of time until the patient is able to void (pass urine), to get up and walk without assistance as well as the time span until the patient is eligible for discharge are evaluated. The occurence of pain as well as the amount of postoperative analgesics needed are documented. One week after the operation, there is a telephone interview with the patient. This includes questions about the occurence of transient neurologic symptoms (a symmetrical bilateral pain in the back or buttocks or pain radiating to the lower extremities after recovery from spinal anesthesia) or postpunctural headache. The interviewer also assesses the patient`s overall satisfaction concerning anaesthesia.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to

future patients undergoing minor perianal surgery in an ambulatory setting by establishing a drug with fewer adverse side effects for this purpose. Both drugs compared in this study are well established. There are no furthers risks than those of regular spinal anaesthesia in an ambulatory setting.

Where is the study run from?
The study has been set up by the Department of Anaesthesiology and Surgical Intensive Care Medicine, University Medical Centre Mannheim.

When is the study starting?
The study started at the day surgery centre, University Medical Centre Mannheim on July 26 2011. Participants will be enrolled on the study for a period of one week starting with the day of surgery.

Who is funding the study?
Funding has been provided by the University Medical Centre Mannheim.

Who is the main contact?
Marc D. Schmittner, MD, PhD
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Contact information

Type(s)
Scientific

Contact name
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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 0.5ml hyperbaric prilocaine 2% versus 0.5ml hyperbaric mepivacaine 4% for low-dose spinal anaesthesia in patients undergoing perianal surgery in an ambulatory setting

Study objectives
In 2010 hyperbaric prilocaine 2% was introduced in the German market. Evidence based data comparing hyperbaric prilocaine 2% versus hyperbaric mepivacaine 4% for perianal surgery does not exist. In this trial we compare the expansion of low dose spinal anaesthesia, the incidence of transient neurological symptoms (TNS) and the duration of stay in hospital comparing 0.5ml hyperbaric prilocaine 2% vs. 0,5ml hyperbaric mepivacaine 4%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee II, Faculty of Medicine, Ruprecht Karl University of Heidelberg [Medizinische Ethikkommission II: MEdizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg], 20 July 2011, ref. AZ.:2011-298N-MA

Study design
Randomised controlled double-blinded single-center 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal diseases

Interventions
Participants are randomised (1:1) and assigned to a dose of either 0.5ml of hyperbaric prilocaine 2% or of 0.5ml of hyperbaric mepivacaine 4%.

The expansion of sensory and motor blocks are tested. After the procedure, the period of time until the patient is able to void, to get up and walk without assistance as well as the time span until the patient is eligible for discharge are evaluated. The occurence of pain as well as the amount of postoperative analgesics needed are documented. One week postoperative a

telephone-interview with the patient is carried out. This includes questions about the occurence of transient neurologic symtoms or postpunctural headache. The interviewer also asseses the patient's overall satisfaction concerning anaesthesia.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Period of time till discharge
2. Occurence of transient neurologic symptoms

Secondary outcome measures
1. Occurence of pain
2. Patients satisfaction
3. Expansion of sensory and motor block
4. Time span until patient is able walk and void

Overall study start date
26/07/2011

Completion date
26/05/2012

Eligibility

Key inclusion criteria
1. Patients (male or female) undergoing minor perianal surgery
2. Aged 18 - 80 years
3. American Society of Anesthesiologists (ASA) physical status I-III

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria

1. Contraindications for spinal anaesthesia
2. Allergy to diclofenac, metamizole, paracetamole, piritramid or one of the local anaesthetics used
3. Patients with language barriers

Date of first enrolment
26/07/2011

Date of final enrolment
26/05/2012

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Centre Mannheim [Universitätsmedizin Mannheim]
Mannheim
Germany
68167

Sponsor information

Organisation
University Medical Centre Mannheim [Universitätsmedizin Mannheim] (Germany)

Sponsor details
Department of Anaesthesiology and Intensive Care Medicine
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Sponsor type
University/education

Website
http://www.umm.de/

ROR
https://ror.org/05sxbyd35

Funder(s)

Funder type
University/education

Funder Name
University Medical Centre Mannheim [Universitätsmedizin 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