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27G-Quincke® vs 27G-Pencil-Point® spinal needles for spinal saddle block

Submission date	Recruitment status	[ ] Prospectively registered
22/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/05/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/05/2009	Nervous System Diseases	[ ] 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 27G-Quincke® vs 27G-Pencil-Point® spinal needles and 10 vs 30 minutes fixation time for spinal saddle block regarding the incidence of post-dural puncture headache

Study objectives
The incidence of post-dural puncture headache in spinal saddle block seems to be associated with the time given for fixation of the local anaesthetic. Under the assumption of an elevated cerebro-spinal-fluid pressure in the lumbar spine in the sitting position we hypothesised that (a) using a 27G-Pencil-Point® spinal needle instead of a 27G-Quincke-type® spinal needle AND (b) leaving the patient in the upright position for fixation of the local anaesthetic for 10 instead of 30 minutes would reduce the incidence of post-dural-puncture headache.

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), approved on 27/09/2008.

Study design
Randomised controlled single-centre 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
Post-dural puncture headache

Interventions
Patients are randomised 1:1:1:1 to:

A: 27-gauge Quincke® needle, being left in the upright postion for 10 minutes
B: 27-gauge Quincke® needle, being left in the upright postion for 30 minutes
C: 27-gauge Pencil-Point® needle, being left in the upright postion for 10 minutes
D: 27-gauge Pencil-Point® needle, being left in the upright postion for 30 minutes

Patients receive a questionnaire and phone call one week later to obtain information about satisfaction and occurring complications. The time for the performance of the spinal anaesthesia and problems with the handling of the spinal needle are recorded by the anaesthesiologist.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incidence of post-dural puncture headache and other complications, measured one week after anaesthesia.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2008

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. Patients (male/female) with minor perianal surgery
2. Age 18-80 years
3. American Society of Anesthesiologists (ASA) physical status I-III
4. No contraindications for spinal anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Contraindications for spinal anaesthesia
2. Allergy to local anaesthetics

Date of first enrolment
01/09/2008

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin Mannheim
Mannheim
Germany
69167

Sponsor information

Organisation
B. Braun Melsungen AG (Germany)

Sponsor details
Carl-Braun-Strasse 1
Melsungen
Germany
34212

Sponsor type
Industry

Website
http://www.bbraun.com

ROR
https://ror.org/04nxj7050

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg (Germany) - main funder

Funder Name
B. Braun Melsungen AG (Germany) - provided the spinal needles

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