

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

Submission date 22/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/05/2009	Condition category Nervous System Diseases	<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

Contact name

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Contact details

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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 position for 10 minutes

B: 27-gauge Quincke® needle, being left in the upright position for 30 minutes

C: 27-gauge Pencil-Point® needle, being left in the upright position for 10 minutes

D: 27-gauge Pencil-Point® needle, being left in the upright position 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