

Headache after dural puncture - influence of cerebrospinal liquid pressure

Submission date 06/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/07/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Protocol serial number
N/A

Study information

Scientific Title
Correlation of cerebrospinal fluid opening pressure and the incidence of post-dural puncture headache after spinal saddle-block

Study objectives
The incidence of post-dural puncture headache seems to be associated with cerebrospinal fluid pressure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee (med. Ethikkommission II; Medizinische Fakultät Mannheim der Ruprechts-Karls-Universität Heidelberg) approved on the 15th December 2008

Study design

Single centre non-randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-dural puncture headache

Interventions

Using a 27 gauge Quincke needle for spinal anaesthesia in saddle block technique, measuring the cerebrospinal fluid pressure by using a spinal fluid manometer.

All patients were treated according a clinical standard: after dural puncture the dural opening pressure was measured and 1.0 ml cerebrospinal fluid (CSF) preserved. Ambulatory patients receive 1.0 ml scandicaine 4% hyperbaric; in house patients receive 1.0 ml bucaine 0.5% hyperbaric; all patients received a telephone-call 1 week after surgical intervention to obtain information about complications concerning the spinal anaesthesia.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Post-dural puncture headache and other complications within 7 days.

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/09/2009

Eligibility

Key inclusion criteria

1. Male/female patients with minor perianal surgery
2. Aged 18 - 80 years
3. American Society of Anaesthesiologists (ASA) grade I - III
4. No contraindications for spinal anaesthesia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Contraindications for spinal anaesthesia
2. Allergy to local anaesthetics

Date of first enrolment

15/04/2009

Date of final enrolment

01/09/2009

Locations**Countries of recruitment**

Germany

Study participating centre

Theodor-Kutzer-Ufer 1-3

Mannheim

Germany

68167

Sponsor information**Organisation**

B. Braun Melsungen AG (Germany)

ROR

<https://ror.org/04nxj7050>

Funder(s)

Funder type

Industry

Funder Name

B. Braun Melsungen AG (Germany) - provided spinal needles and equipment

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration