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Headache after dural puncture - influence of cerebrospinal liquid pressure

Submission date	Recruitment status	[ ] Prospectively registered
06/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/07/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/07/2009	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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68167

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non 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
Post-dural puncture headache

Interventions
Using a 27 gauche 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 clincal 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 measure
Post-dural puncture headache and other complications within 7 days.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/04/2009

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 Anaesthesioloists (ASA) grade I - III
4. No contraindications for spinal anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 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
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)

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
Industry

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

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