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25- versus 29-gauge Quincke spinal needles

Submission date 12/12/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 20/03/2008	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/03/2008	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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
anaesMA2007-03

Study information

Scientific Title

Comparison of 25- versus 29-gauge Quincke spinal needles for minor anorectal surgery as well as abdominal caesarean section in respect of patient satisfaction and handling

Study objectives
It is considered, that the incidence of post-puncture dural headache is correlated with the size of the spinal needle. For reason of patients' satisfaction and to minimize complications, a 29-gauge spinal needle is suitable for this purpose, especially in pregnant patients and patients undergoing ambulatory surgery. Though, the handling of this very thin spinal needle is described as difficult and therefore denied by several anaesthesiologists.

The aim of this study is to evaluate the patients' satisfaction, the incidence of post-puncture dural headache and the handling conditions for the anaesthesiologist.

Hypothesis:
The performance of a spinal anaesthesia with 29-gauge compared to a 25-gauge Quincke needles has a lower incidence of complications in patients undergoing minor anorectal surgery and abdominal caesarean section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Medizinische Ethik-Kommission II: Medizinische Fakultat Mannheim der Ruprecht-Karls-Universitat Heidelberg) on the 19th September 2007 (ref: 2007-236N-MA).

Study design
Single centre, randomised controlled 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-puncture dural headache

Interventions
The patients are 1:1 randomised to either a 25-gauge or a 29-gauge spinal needle. Patients receive a questionnaire 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 Specified

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

Secondary outcome measures
Time for the performance of spinal anaesthesia and occurring complications, measured one week after anaesthesia.

Overall study start date
01/02/2008

Completion date
31/01/2009

Eligibility

Key inclusion criteria
1. Patients (male/female) with minor anorectal surgery, or
2. Patients (female) for abdominal caesarean section
3. Age 18 - 80 years
4. American Society of Anaesthesiology (ASA) grade I - III
5. No contraindications for spinal anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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

Date of first enrolment

01/02/2008

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
Germany

Study participating centre
University Clinic Mannheim
Mannheim
Germany
68167

Sponsor information

Organisation
B. Braun Melsungen AG (Germany)

Sponsor details
Carl-Braun-Strasse 1
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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 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