

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

Protocol serial number

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 Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg) on the 19th September 2007 (ref: 2007-236N-MA).

Study design

Single centre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration