

# 25- versus 29-gauge Quincke spinal needles

<b>Submission date</b> 12/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/03/2008	<b>Condition category</b> Signs and Symptoms	<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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## 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 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

### **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

Melsungen

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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