

# Comparison of anaesthesia methods: single-shot ultrasound guided interscalene block, general anaesthesia and the combination of both, for minor shoulder surgery

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| <b>Submission date</b><br>07/10/2011   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>15/03/2012 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>15/03/2012       | <b>Condition category</b><br>Musculoskeletal 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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## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

Randomized prospective clinical study for evaluation of practicability, postoperative analgetic consumption and patients' satisfaction of patients undergoing minor shoulder surgery with ultrasound guided single-shot interscalene plexus block versus total anesthesia versus combination of both methods.

## Study objectives

Minor shoulder surgery can be performed with several anaesthesia techniques. Patients and doctors, have currently uncertainties about the anaesthesia which should be performed for minor shoulder surgery. Due to multiple irrational fears, many patients deny local anaesthesia and prefer a general anaesthesia. Anaesthesiologists are concerned about sufficient pain management when performing only a ultrasound guided interscalene single-shot plexus block.

In this study we evaluate the practicability, complications, patients' satisfaction and the analgetic consumption for total anaesthesia versus ultrasound guided interscalene block versus the combination of both methods.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethics Committee II, Faculty of Medicine, Ruprecht Karl University of Heidelberg [Medizinische Ethikkommission II: Medizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg], 27 January 2011 ref: AZ.2010-355N-MA

## Study design

Randomised prospective controlled single centre trial

## Primary study design

Interventional

## Study type(s)

Quality of life

## Health condition(s) or problem(s) studied

Minor shoulder surgery

## Interventions

Participants are randomised (1:1:1) to either ultrasound guided single-shot interscalene plexus block or total anesthesia or combination of both techniques. When performing an interscalene plexus block the expansion of anaesthesia is tested by discrimination of warm and cold.

Duration, complications and quality of the performed interscalene block are documented as well as need for additional analgetic treatment and pharmaceuticals used for total anaesthesia. Patients are treated with a standard analgetic scheme and are asked to fill in a questionnaire 24 hours after surgery.

## Intervention Type

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Diclofenac

**Primary outcome(s)**

1. Analgesic consumption
2. Duration of anaesthesia, recovery room stay and hospitalisation

**Key secondary outcome(s)**

1. Practicability
2. Patients satisfaction

**Completion date**

01/10/2012

## **Eligibility**

**Key inclusion criteria**

1. Patients (male/female) undergoing minor shoulder arthroscopy
2. Aged 18-80 years
3. American Society of Anesthesiologists (ASA) physical status I-III
4. No contraindications for interscalene plexus block and/or general anaesthesia

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

Male

**Key exclusion criteria**

1. Contraindications for interscalene plexus block and/or general anaesthesia
2. Allergy to diclofenac

**Date of first enrolment**

27/07/2011

**Date of final enrolment**

01/10/2012

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

**University Medical Centre Mannheim**

Mannheim

Germany

68167

## Sponsor information

**Organisation**

University Medical Centre Mannheim [Universitätsmedizin Mannheim] (Germany)

**ROR**

<https://ror.org/05sxbyd35>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University Medical Centre Mannheim [Universitätsmedizin Mannheim] (Germany)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration