

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

Submission date 07/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/03/2012	Overall study status Completed	☐ Protocol
Last Edited 15/03/2012	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ 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

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