Comparison of anaesthesia methods: singleshot 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 Protocol
Registration date 15/03/2012	Overall study status Completed	 Statistical analysis plan Results
Last Edited 15/03/2012	Condition category Musculoskeletal Diseases	Individual participant dataRecord updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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 curently 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 singe-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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 documentated 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 measure

Analgesic consumption
 Duration of anaesthesia, recovery room stay and hospitalisation

Secondary outcome measures

Practicability
 Patients satisfaction

Overall study start date

27/07/2011

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

Age group Adult

Lower age limit 18 Years

Upper age limit

80 Years

Sex

Male

Target number of participants 120

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)

Sponsor details Department of Anaesthesiology and Intensive Care Medicine [Klinik für Anästhesiology und Operative Intensivmedizin] Theodor-Kutzer-Ufer 1-3 Mannheim Germany 68167 marc.schmittner@umm.de

Sponsor type Hospital/treatment centre

Website http://www.umm.de/

ROR https://ror.org/05sxbyd35

Funder(s)

Funder type University/education

Funder Name University Medical Centre Mannheim [Universitätsmedizin Mannheim] (Germany)

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