ISRCTN84074316 https://doi.org/10.1186/ISRCTN84074316

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

Registration date
15/03/2012

Overall study status
Completed

Last Edited
15/03/2012

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Contact name
Dr Marc Schmittner

Contact details
University Medical Centre Mannheim
[Universitätmedizin Mannheim]
Department of Anaesthesiology and Intensive Care Medicine
[Klinik für Anästhesiologie und Operative Intensivmedizin]
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167
marc.schmittner@umm.de

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

Secondary outcome measures
1. Practicability
2. 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