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Comparison of two regional anesthesia techniques (interscalene versus subacromial block) for pain relief after a specific arthroscopic shoulder operation (rotator cuff tear repair)

Submission date
18/09/2015

Recruitment status
No longer recruiting

Registration date
25/09/2015

Overall study status
Completed

Last Edited
25/09/2015

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The rotator cuff is a group of muscles and tendons that surround the shoulder joint. When the tendons are “torn” away from the shoulder bone, this is known as a rotator cuff tear. This is one of the most common types of shoulder pain, especially in people who perform repeated overhead motions, such as playing tennis. Rotator cuff tears can happen suddenly from an injury, or develop gradually over time. If a rotator cuff tear is so severe that it cannot heal on its own, an operation called a rotator cuff repair is recommended. A rotator cuff repair involves stitching the torn tendon back onto its attachment on the upper arm bone (humerus). Although patients are sedated during the operation, they usually receive a local anaesthetic injection around the nerves in the neck to numb the shoulder and arm (regional anaesthesia) to prevent pain afterwards. The gold standard of regional anaesthesia is the “interscalene block”, which is done before the operation. Although this technique is widely used, it can have rare but serious side effects, such as difficulty breathing or permanent damage to the nerves. An alternative to the interscalene block is the subacromial block. This technique involves injecting the anaesthetic between the shoulder blade and humerus after the operation. However, more research is needed to find out whether this is as successful at providing pain relief as the interscalene block. The aim of this study is to compare how effective the subacromial block or interscalene block are at providing pain relief after rotator cuff surgery.

Who can participate?
Adults undergoing rotator cuff tear repair surgery.

What does the study involve?
Participants are randomly allocated into one of two groups. Patients in the first group receive the interscalene block, which is placed before the operation and patients in the second group receive the subacromial block, which is placed after the operation. After the surgery, patients

remain in hospital for three days. Pain levels and shoulder movement are recorded throughout their stay. They then attend an outpatient appointment once a month for a further four months.

What are the possible benefits and risks of participating?
There are no specific benefits of participating. Possible risks of participating are that patients in the subacromial block group may need higher doses of pain killers which have recorded side effects (e.g. vomiting constipation, sleepiness). Participants in the interscalene block group risk the known complications of this technique.

Where is the study run from?
Hôpital de Saint Loup (Switzerland)

When is the study starting and how long is it expected to run for?
March 2011 to June 2015

Who is funding the study?
Hôpital de Saint Loup (Switzerland)

Who is the main contact?
Mrs Angeliki Paneri

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
103/11

Study information

Scientific Title
Effectiveness of subacromial versus interscalene continuous infusion of ropivacaine for pain management after arthroscopic rotator cuff repair

Study objectives

The aim of this study is to investigate whether the subacromial block more effective in terms of pain scores than the interscalene block.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Commission of research ethics in humans (Commission cantonale d'éthique de la recherche sur l'être humain), 11/04/2011, ref: 103/11

Primary study design
Interventional

Study design
Randomized non-blinded prospective interventional single-center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain treatment after arthroscopic rotator cuff tear repair

Interventions
Based on a computer generated randomization table, 126 adult patients undergoing arthroscopic rotator cuff tear repair are assigned to either the interscalene group or the subacromial group. All patients underwent the operation under general anesthesia, the interscalene group have the catheter placed by the anesthesiologist before the operation, the subacromial catheter was placed by the surgeon at the end of the operation.They both have the same continuous infusions of local anesthetic (ropivacaine 0.2% 4ml/h) initiated at the recovery room and during the three day hospitalization. Pain scores, patients' satisfaction, shoulder movement and side effects were noted during the hospitalization, as well as at the surgeon's consultation once a month for four months.

Intervention Type
Other

Primary outcome(s)
Pain measured using the visual analogue score (VAS) at rest three times per day and before and after physiotherapy twice a day during the three day hospitalization.

Key secondary outcome(s)
1. Amplitude of shoulder movement measured using a goniometer during in-hospital physiotherapy (twice per day) and once a month at the surgeon's consultation after discharge for four months
2. Patients' satisfaction measured at the time of discharge using an inverse visual analog scale
3. Side effects (nausea, infection, hematoma, neurological problems, pneumothorax, Horner's syndrome, hoarseness, respiratory distress, capsulitis) as noted by medical personnel during the period of hospitalisation

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. ASA physical status I-III
3. Undergoing a rotator cuff tear repair

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Allergy to one of the drugs
2. Coagulopathy
3. Renal failure
4. Hepatic failure
5. Severe respiratory disease
6. Peripheral neuropathy of the upper limb
7. Paralysis of the controlateral phrenic nerve
8. Chronic opioid treatment

Date of first enrolment
28/06/2011

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Switzerland

Study participating centre

EHNV Hôpital de Saint Loup
Pompaples
Switzerland
1318

Sponsor information

Organisation
Hôpital de Saint Loup

ROR
https://ror.org/02t7mb865

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hôpital de Saint Loup

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request