# 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	Recruitment status	Prospectively registered
18/09/2015	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
25/09/2015	Completed	[_] Results
Last Edited	Condition category	Individual participant data
25/09/2015	Surgery	[] 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

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

#### Study design

Randomized non-blinded prospective interventional single-center study

**Primary study design** Interventional

Secondary study design Randomised parallel trial

Study setting(s) Hospital

**Study type(s)** Treatment

**Participant information sheet** Not available in web format

#### 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 measure

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.

#### Secondary outcome measures

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

#### Overall study start date

20/03/2011

#### **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

#### Age group

Adult

#### **Lower age limit** 18 Years

#### Sex

Both

**Target number of participants** 126 patients (randomized in blocks of 10)

#### 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

**Sponsor details** Etablissements Hospitaliers du Nord Vaudois Pompaples Switzerland 1318

**Sponsor type** Hospital/treatment centre

Website www.saint-loup.ch

ROR https://ror.org/02t7mb865

## Funder(s)

**Funder type** Hospital/treatment centre **Funder Name** Hôpital de Saint Loup

## **Results and Publications**

**Publication and dissemination plan** Manuscript sent to BMC anesthesiology

Intention to publish date 01/11/2015

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Available on request