

# Visability during arthroscopic shoulder surgery: influence of epinephrine

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To determine whether the use of epinephrine saline irrigation in therapeutic shoulder arthroscopy with need for subacromial procedures should significantly increase clarity of the view.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON38382

### Source

ToetsingOnline

### Brief title

Visability during arthroscopic shoulder surgery: influence of epinephrine

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

impingement syndrome, shoulder tendon

### Research involving

Human

### Sponsors and support

**Primary sponsor:** orthopaedie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** arthroscopic, epinephrine, shoulder, visibility

## Outcome measures

### Primary outcome

The difference in intra-operative clarity of the visual view between epinephrine and placebo subjects in: Mean VAS score; the main study parameter is a 2-point difference (20 %).

### Secondary outcome

Difference in mean blood pressure, potential cardiovascular adverse reactions and serum epinephrine levels.

## Study description

### Background summary

Arthroscopy of the shoulder is increasingly developing due to the rise of number of patients to treat and the increasing possibility to use arthroscopy for diagnostics and treatment.

To perform an arthroscopic operation safely an optimal view is essential. The most common factor impairing the clarity of the visual view is intra-articular and or subacromial bleeding. To achieve this optimal view previous studies used techniques that directly aimed at controlling the bleeding, using thermal electrocautery devices and pressurized irrigation systems. These techniques increase the intra-articular joint space and the fluid flow removes debris and blood. However, optimal view cannot always be acquired.

Anecdotic observations in clinical practice, at our institute and in literature suggest that the use of epinephrine added to the irrigation fluid used in knee and shoulder arthroscopy minimizes intra-operative bleeding hence increasing the view. Information about the effectiveness of adding epinephrine to irrigation fluid in subjects undergoing shoulder arthroscopy with the need for subacromial procedures is scarce.

(seen background protocol 1.0)

### Study objective

To determine whether the use of epinephrine saline irrigation in therapeutic shoulder arthroscopy with need for subacromial procedures should significantly increase clarity of the view.

## Study design

Prospective, randomized, double-blinded, placebo-controlled study

## Study burden and risks

A good intra-operative view is essential in performing arthroscopic shoulder surgery. Therefore this study provides an excellent model to study differences in visibility. Ultimately this may lead to better identification and treatment of subjects with shoulder pathology.

The burden for the participants is limited to a total of three venous blood samples taken before and after the surgery using a already placed IV. To assess the decrease in bleeding epinephrine is added to the irrigation fluid. The risks associated with this drug exposure are, in this type of use rare (see background). Possible adverse reactions include: palpitations, tachycardia, arrhythmia, anxiety, headache, tremor, hypertension and acute pulmonary edema.

## Contacts

### Public

Selecteer

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### Scientific

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Patients that are willing and able to participate in the study protocol
- Patients in need of arthroscopic shoulder surgery based on; a Bankart- or SLAP-lesion, a rotator cuff lesion, an impingement syndrome and or AC-joint pathology.

### Exclusion criteria

- patients with known cardiac diseases/ arrhythmia
- age under eighteen years
- language barrier
- mental disabilities
- Uncontrolled hypertension (\* 180/110)
- Hypokalaemia
- Atopic asthma
- Constitutional allergy
- Sulphite allergy
- increased surgical risk( ASA >3)

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 10-09-2010  
Enrollment: 126  
Type: Actual

## Medical products/devices used

Product type: Medicine  
Brand name: epinephrine 1 mg/ml  
Generic name: EPINEFRINE CF  
Registration: Yes - NL outside intended use

## Ethics review

Approved WMO  
Date: 07-07-2010  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 11-12-2012  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
EudraCT	EUCTR2009-016696-30-NL
CCMO	NL30185.098.09