Visability during arthroscopic shoulder surgery: influence of epinephrine

Published: 07-07-2010
Last updated: 04-05-2024

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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	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 cardiovasculair 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 electrocauthery 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

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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/ arrhithmia
- 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) metc-ldd@lumc.nl

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