Cryotherapy in the recovery of bursectomy for subacromial pain syndrome. A pragmatic randomized controlled trial.

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The purpose of this study is to investigate the value of postoperative cryotherapy on subjective patients-reported pain; shoulder function and quality of life in patients operated for SAPS .

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Synovial and bursal disorders
Study type	Interventional

Summary

ID

NL-OMON43182

Source
ToetsingOnline

Brief title
CRYO-study

Condition

- Synovial and bursal disorders
- Soft tissue therapeutic procedures

Synonym
Impingement, Subacromial Pain syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: maatschap orthopedie/onderzoeksfonds Alrijne Ziekenhuis

Intervention

Keyword: cooling, cryotherapy, Impingement syndrome, shoulder

Outcome measures

Primary outcome

Quality of life reported by the patient using a disease specific questionaire

(Westen Ontario Rotator Cuff Index (WORC)) 8 weeks after surgery.

Secondary outcome

Pain reported on a Visuele Analogue Scale (VAS) (baseline, 2 weeks, 8 weeks , 3

months and 1 year after surgery).

Postoperative pain reported on a numeric rating scale (NRS), first 8 weeks

after surgery using a pain-diary.

Postoperative use of painkillers, first 2 weeks after surgery using a

pain-diary.

Simple Shoulder Test (baseline, 2 weeks, 8 weeks, 3 months and 1 year after

surgery)

Constant Score (baseline, 2 weeks, 8 weeks, 3 months and 1 year after surgery)

Range of motion (baseline, 2 weeks, 8 weeks, 3 months and 1 year after surgery)

Schouderkracht (baseline, 2 weeks, 8 weeks, 3 months and 1 year after surgery)

WORC (baseline, 2 weeks, 3 months and 1 year after surgery)

Study description

Background summary

Most patient will experience pain after arthroscopic debridement of the bursa. We know from different surgical procedures and earlier investigation of shoulder surgery that postoperative pain predict final recovery of the shoulder. By improving our postoperative management of pain we aim to improve theresults of the operation.
Computer assisted cryotherapy may lead to reduction of experienced pain, and might be a valueble option (next to to local techniques and the use of medication). The effect of cryotherapy has been attributed the inhibition of the inflammatory cascade, and reduction of tissue oedema or hematoma. Using a computer we are able to cool the shoulder to a more constant temperature at 10-14 degrees Celcius, and thus potentially resulting in a greater effect of cooling. Unfortunately, it is unknown whether postoperative cryotherapy leads to reduced pain, early mobilization of the shoulder and improved quality of life after arthroscopy of the shoulder.

Study objective

The purpose of this study is to investigate the value of postoperative cryotherapy on subjective patients-reported pain; shoulder function and quality of life in patients operated for SAPS .

Study design

Randomized clinical trial

Intervention

Groep A: Computer-assisted cryotherapie
Groep B: Usual Care with subacromial levobupivaicaine 20mL (5mg/mL, 0,5% chirocaine).

Study burden and risks

There is a small risk of a comprised circulation of the skin, which may result in cold urticarea (estimated risk <1%)
Theoretically, there is an elevated risk that a deprived inflammatory cascade may increase the risk of infection.

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

- Pain localized in the deltoid region
- Complaints for more than 6 months
- Unsuccessful physical therapy for at least six weeks
- Exacerbation of pain when raising the arm
- A positive Neer impingement sign, and an only temporarily effect of ultrasound guided subacromial infiltration (lidocain + corticosteroids).
- A positive Hawkins-Kennedy test
- A painful arc
- Scheduled for arthroscopic bursectomy

Exclusion criteria

- No informed consent is obtained
- Language barrier
- Age <25 years
- Full-thickness rotator cuff tear
- Restriction of passive shoulder motion (i.e. frozen shoulder).
- Glenohumeral osteoarthritis
- Calcifying tendonitis
- History of a neurological disorder (e.g. stroke, Parkinson, dementia)
- Rheumatoid arthritis
- Concomitant biceps tenodesis/tenotomy.
- Subacromial decompression (Those patients are treated with a pain-buster).
- Clinical signs of cervical radiculopathy.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2017
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Computer-assisted cryotherapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-12-2016
Application type:	First submission
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
CCMO	NL58789.058.16