

# 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 .

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Synovial and bursal disorders
<b>Study type</b>	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 questionnaire (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 the results of the operation.

Computer assisted cryotherapy may lead to reduction of experienced pain, and might be a valuable option (next 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 levobupivacaine 20mL (5mg/mL, 0,5% chirocaine).

## Study burden and risks

There is a small risk of a compromised circulation of the skin, which may result in cold urticaria (estimated risk <1%)

Theoretically, there is an elevated risk that a deprived inflammatory cascade may increase the risk of infection.

## Contacts

### Public

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### Scientific

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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