“De invloed van cryotherapie op het postoperatief herstel na een schouderoperatie voor het subacromiaal pijnsyndroom.”

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25969

Source
Nationaal Trial Register

Brief title
Cryo-study

Health condition

Postoperative pain and shoulder function after bursectomy for subacromial pain syndrome.

Sponsors and support

Primary sponsor: C.P.J. Visser (CV), M.D., PhD
Orthopaedic Surgeon
Alrijne hospital
Department of Orthopedics
Source(s) of monetary or material Support: No financial support from other sources.

Intervention

Outcome measures

Primary outcome

The primary study outcome is quality of life reported on the Western Ontario Rotator Cuff index 8 weeks after surgery.

Secondary outcome

Secondary outcomes are VAS for pain in rest, VAS when elevating the arm, Simple Shoulder test, Constant Score, range of motion, use of painkillers and return to work. Additionally, we will daily record pain and use of painkillers until approximately 8 weeks after surgery.

Study description

Background summary

Rationale: Pain and early mobilization are essential factors affecting postoperative recovery after shoulder surgery. In spite of being one of the oldest empirical treatments to relieve pain after (surgical) musculoskeletal trauma, cryotherapy is not universally provided after shoulder
surgery. It is unknown whether postoperative cryotherapy leads to a reduction of experienced
pain, early mobilization and improved quality of life after arthroscopic shoulder surgery.

Objective: To study the effectiveness of postoperative cryotherapy on subjective patientreported
pain and shoulder function in patients operated for subacromial pain syndrome.
Study design: Randomized controlled trial, Level of evidence 1b.

Study population: The study population consists 70 patients with subacromial pain syndrome (SAPS) who are treated with an arthroscopic debridement of the bursa.
Intervention: 35 patients (intervention group) will be allocated to computer-assisted cryotherapy (Zamar® ZTCube) for 2 to 8 weeks after surgery. 35 patients (control group) will be allocated to receive usual care treatment with 20mL subacromial levobupivacain (5mg/mL, 0,5%, Chirocaine) injection after finishing the surgical procedure.

Main study endpoint: The primary study outcome is quality of life reported on the Western Ontario Rotator Cuff index 8 weeks after surgery. Secondary outcomes are VAS for pain in rest, VAS when elevating the arm, Simple Shoulder test, Constant Score, range of motion, use of painkillers and return to work. Outcomes are obtained at 2 weeks, at 8 weeks, at 3 months and 1 year after surgery. Additionally, we will daily record pain and use of painkillers until approximately 8 weeks after surgery. We will apply mixed models to investigate the

effectiveness of computer-assisted cryotherapy.

Study objective

We hypothesized that computer-assisted cryotherapy leads to a significant reduction of postoperative patient-reported pain and increase in shoulder function in patients operated for patients with SAPS.

Study design

Outcomes are assessed at baseline, 2 weeks, at 8 weeks, at 3 months and 1 year after surgery.

Intervention

35 patients (intervention group) will be allocated to computer-assisted cryotherapy (Zamar® ZTCube) for 2 to 8 weeks after surgery. 35 patients (control group) will be allocated to receive usual care treatment with 20mL subacromial levobupivacain (5mg/mL, 0,5%, Chirocaine) injection after finishing the surgical procedure.

Contacts

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Eligibility criteria

Inclusion criteria

SAPS is defined according to the recommendations published in the guidelines for the diagnosis and treatment of SAPS of the Dutch orthopaedic association7. Emphasis is put on a combination of tests to demonstrate SAPS7, 25. The following inclusion criteria are applied:

- 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.

- Subacromial decompression (Those patients are treated with a pain-buster).

- Clinical signs of cervical radiculopathy.

Study design

Design

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

Recruitment

NL

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

Ethics review

Positive opinion

Date:	20-04-2017
Application type:	First submission

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
NTR-new	NL6239
NTR-old	NTR6419
Other	58789, ABR nummer : P16.212, METC leiden

Study results