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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25969

Bron
Nationaal Trial Register

Verkorte titel
Cryo-study

Aandoening

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

Ondersteuning

Primaire sponsor: C.P.J. Visser (CV), M.D., PhD
Orthopaedic Surgeon
Alrijne hospital
Department of Orthopedics
Overige ondersteuning: No financial support from other sources.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-04-2017
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6239
NTR-old	NTR6419
Ander register	58789, ABR nummer : P16.212, METC leiden

Resultaten