Dutch Frozen Shoulder Study

No registrations found.

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

Summary

ID

NL-OMON27236

Source
Nationaal Trial Register

Brief title
D-FROST

Health condition

Frozen Shoulder, Adhesive capsulitis

Sponsors and support

Primary sponsor: Nvt
Source(s) of monetary or material Support: No funding yet

Intervention

Outcome measures

Primary outcome

SPADI

Secondary outcome

Pain: Numeric Pain Rating Scale (NPRS).

Patient perceived satisfactory improvement (PPSI) (Klooster 2006)

Health related quality of life: RAND-36 (Dutch validated SF-36)

Passive Range of Motion (ROM)

Study description

Background summary

SUMMARY

Rationale: Adhesive capsulitis (frozen shoulder) is a common cause of shoulder pain and affects approximately 2-4% of the general population. Corticosteroid injections and physiotherapy are among the most widely used treatment modalities in adhesive capsulitis, in both primary and secondary healthcare settings. According to the current literature, there is no consensus on the role of physiotherapy in the treatment of frozen shoulder. In other words, it is uncertain whether physiotherapy is of clinical relevant additional value above an intra-articular corticosteroid injection alone.

Objective: To evaluate the difference in functional outcome, measured by a patient self-reported outcome measure, the SPADI, after treatment of adhesive capsulitis with or without physiotherapy.

Study design: (multicenter) Prospective randomised trial

Study population: Adult patients with clinical signs and symptoms of a frozen shoulder presenting to the outpatient clinic of the department of orthopaedic surgery of the participating hospitals. Conservative treatment has failed in the previous three months. As part of the standard current practice, all patients with a frozen shoulder in both groups receive an ultrasound guided corticosteroid injection in the glenohumeral joint.

Intervention: A standardised physiotherapy program.

Main study parameters/endpoints: Primary outcome: Function, measured by the SPADI Secondary outcomes: Pain (Numeric Pain Rating Scale). General health (RAND 36), ROM, patient perceived satisfaction (PPSI)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjective scores to fill out, and an increased number of (non-invasive) measurements of the function of the shoulder. Follow up consists of three moments at 6 weeks, 3 months and 6 months. Participating physiotherapists will be provided with a written treatment protocol containing detailed guidelines for these frozen shoulder patients. The benefit of the study is to provide an answer to the question if we have to treat a patient with a frozen shoulder with a physiotherapy program after a corticosteroid injection. This trial can

also aid in the development of a guideline for physiotherapist in the treatment of frozen shoulders. If physiotherapy appears to be of no additional value, this can save a lot of time, effort and money for patients and the healthcare system

Study objective

A benificial effect of physiotherapy in the treatment of a frozen shoulder

Study design

6 weeks, 3 months, 6 months

Intervention

Physiotherapy

Contacts

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Eligibility criteria

Inclusion criteria

• Age □ 25 years

• Clinical signs of frozen shoulder being:
Symptoms of pain and stiffness, predominantly in one shoulder, persisting ≥ 3 months, without preliminary trauma.

Restriction of passive motion in the glenohumeral joint with scapular stabilisation of ≥30° in external rotation and a second plane of movement, measured to onset of pain.

• Unsuccessful conservative therapy within the previous 3 months

• VAS ≥ 6

Exclusion criteria

• Previous corticosteroid injection in the shoulder region within 6 weeks

• Evidence of a complete rotator cuff tear on physical examination, ultrasound images or MRI

• Acute subacromial/subdeltoid bursitis

• Osteoarthritis of the glenohumeral or acromioclavicular joint, Kellgren-Lawrence osteoarthritis grading scale ≥ 2

• Previous surgery to the shoulder

• Systemic inflammatory joint disease

• Neurological disorders upper limb

• Therapeutic anticoagulation (INR ≥1.7)

• Other known shoulder pathology such as infection or tumor

• Contra-indication to corticosteroid injection, allergy to contrast or local anaesthetic

• Inability to give informed consent and fill out questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2014
Enrollment:	82
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-05-2014
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	NL4373
NTR-old	NTR4587
Other	:

Study results

Summary results

not yet