Dutch Frozen Shoulder Study

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

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

Samenvatting

ID

NL-OMON27236

Bron
Nationaal Trial Register

Verkorte titel
D-FROST

Aandoening

Frozen Shoulder, Adhesive capsulitis

Ondersteuning

Primaire sponsor: Nvt
Overige ondersteuning: No funding yet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

SPADI

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

6 weeks, 3 months, 6 months

Onderzoeksproduct en/of interventie

Physiotherapy

Contactpersonen

Publiek

Slotervaartziekenhuis
T. Kraal
Amsterdam
The Netherlands

Wetenschappelijk

Slotervaartziekenhuis
T. Kraal
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-02-2014
Aantal proefpersonen:	82
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-05-2014
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	NL4373
NTR-old	NTR4587
Ander register	:

Resultaten

Samenvatting resultaten

not yet