Eccentric Training of the Supraspinatus tendon in Shoulder Impingement syndrome. A pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON32687

Source
ToetsingOnline

Brief title
Eccentric training in SIS

Condition

- Tendon, ligament and cartilage disorders

Synonym
Rotator cuff tendinopathy, shoulder tendon disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Eccentric training, Rotator cuff tendinopathy, Shoulder immingement syndrome, Supraspinatus tendon

Outcome measures

Primary outcome

Main outcome of the study is rcovery, assessed with the Shoulder Disability

Questionnaire.

Secondary outcome

The following secondary outcomes will be used:

- Constant -score, to assess shoulder function

- 2. Shoulder pain questionnaire, to assess the amount of shoulder pain

- 3. Compliance

- 4. Illness perception

- 5. Satisfaction

At the intake (T0), after 6 (T1) and after 12 weeks (T2) the shoulder function

will be assessed with questionnaires and shoulder function tests. Outcomes of

both groups (eccentric strengthening training and usual care) will be compared

to assess the effect of the eccentric strengthening training program.

Study description

Background summary

Shoulder impingement syndrome (SIS) is the most common cause of shoulder pain. Sixty percent of the patients with SIS benefit from physical therapy while in 30 to 40 percent of the cases that receive physical therapy, the symptoms do not resolve. The majority of SIS are the consequence of rotator cuff tendinopathy. Eccentric strengthening exercises are nowadays frequently used in

treatment of tendinopathies, especially in Achilles tendinopathy eccentric training has shown to be effective. Based on the good results with the Achilles tendon, the idea has raised that these results can be extended to the supraspinatus tendon in the treatment of SIS.

Study objective

The main objective is to obtain more evidence in the effects of eccentric strengthening training of the supraspinatus tendon in SIS by comparing the effects eccentric strengthening training with the effects of usual care used in SIS. Secondary objectives are to find out if home exercise is an adequate intervention and to assess the feasibility of the eccentric training program.

Study design

A randomized comparing pilot study will be used to compare an eccentric training group (experimental group) with a usual care group (control group).

Intervention

Subjects of the exercise eccentric training program group will perform eccentric home exercises twice a day, 7 days a week, for 12 weeks. The control group will continue their usual care at the physiotherapy practice

Study burden and risks

This research is not associated with any risks. The worst case that can be expected is that eccentric strengthening training turns out to be less effective than usual care. All measurements take place at the patients physiotherapy practice. T0 will take 30 minutes, T1 and T2 will take 20 minutes, as a result the total costs will be 70 minutes.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1

9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 1. Painful arc of movement during flexion or abduction*
- 2. Positive Neer or Kennedy- Hawkins impingement signs*
- 3. Pain on resisted lateral rotation, abduction or Jobe test*
- 4. Suffering from SIS with an episode of at least three months and less than one year
- 5. Male or female with an age between 18 and 60 years old
* Subjects will be included in study if they have at least one positive finding of these categories

Exclusion criteria

. Frozen shoulder
- 2. Habitual shoulder luxation in the previous 2 years
- 3. (History of) shoulder fracture
- 4. Previous shoulder surgery
- 5. Cervical radiculopathy
- 6. Inflammatory rheumatic diseases
- 7. Other musculoskeletal problems of an upper limb
- 8. Bilateral SIS
- 9. Unable to complete (Dutch) questionnaires

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL24481.042.08