Dry needling and aspiration treatment versus arthroscopic decompression in patients with supraspinatus tendon calcification: a randomised clinical trial.

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To test if dry needling and aspiration treatment is more effective than arthroscopic shoulder decompression in patients with calcification of the supraspinatus tendon.

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

Summary

ID

NL-OMON34963

Source
ToetsingOnline

Brief title
PRIC-study

Condition

- Tendon, ligament and cartilage disorders

Synonym
Shoulder impingement, shoulder injury

Research involving
Human

Sponsors and support

Primary sponsor: Sint Annaziekenhuis
Source(s) of monetary or material Support: Maatschap orthopedie St Anna ziekenhuis

Intervention

Keyword: supraspinatus calcification dry needling

Outcome measures

Primary outcome

Main study endpoints are pain at rest, shoulder function and amount of calcification. Shoulder function is measured using the DASH questionnaire and ROM. Shoulder pain is measured using a VAS score.

Secondary outcome

Secondary endpoints are quality of arm movement, safety of treatment and involved costs. Quality of arm movement will be measured using accelerometers. Safety is measured with recording of any (S)AE*s during the study. The costs per patient will be analysed for each study group.

Study description

Background summary

After failed standard non-surgical treatment of supraspinatus tendon calcification, arthroscopic subacromial decompression (ASD) surgery is considered the treatment of choice. A not often used non-surgical treatment option is dry needling and aspiration-treatment (DNaA). This treatment imposes considerable fewer burdens upon the patient, avoiding a general anaesthetic, shoulder surgery and an overnight stay in hospital. We have some promising experience with this treatment but scientific evidence is lacking. We therefore planned to conduct this clinical trial, comparing DNaA to ASD surgery. Since patients treated with DNaA receive corticosteroids at the end of the procedure, a third study group will be incorporated. This group will be treated with an ultrasound guided injection leaving a depot of corticosteroids in the bursa subacromialis and the supraspinatus tendon, but without the DNaA-treatment.

Study objective

To test if dry needling and aspiration treatment is more effective than

arthroscopic shoulder decompression in patients with calcification of the supraspinatus tendon.

Study design

A single-center, non-blinded, randomised clinical trial with three treatment arms.

Intervention

The study intervention group will receive dry needling and aspiration-treatment of the calcification in the supraspinatus tendon. The first control group will be treated with ASD surgery of the shoulder with debridement of the calcification if possible. The second control group will be treated with an ultrasound guided injection leaving a depot of corticosteroids in the bursa subacromialis and the supraspinatus tendon.

Study burden and risks

Patients consenting to participate will have to return for longer follow ups and more often. Extra scheduled follow ups are once before treatment and three times after treatment. Each visit will take approximately 30 minutes. The involved risks with participation are the standard risks involved with surgery and the expected risks with DNaA-treatment are expected to be less than with surgery, although there is no literature to confirm this. Expected benefits are improvement in shoulder pain and function with less stress placed upon the patient in case of randomisation into the group receiving DNaA-treatment. If patients are allocated to the second control group, they will receive a ultrasound guided injection leaving a depot of corticosteroids in the bursa subacromialis and the supraspinatus tendon, but without the DNaA-treatment. Patients from this group with insufficient relief of symptoms three months after the injection will be offered immediate and appropriate further orthopedic treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients of either sex who have been clinically diagnosed with shoulder impingement. Calcification of the supraspinatus tendon has to be confirmed with both radiography and diagnostic ultrasound.
2. Integrity of the supraspinatus tendon.
3. Calcification diameter > 6 mm visible on a diagnostic radiograph less than six weeks old.
4. Patients may have calcification in one or both shoulders. For patients with bilateral calcifications, both shoulders will be included as separate cases.
5. Shoulder symptoms should be present > 6 months
6. Non-surgical treatment other than dry needling or aspiration has failed to improve symptoms in the previous six months
7. Patients over 18 years old

Exclusion criteria

1. Patients with radiographic or diagnostic ultrasound confirmed calcification of the subacromial bursa or calcification of the subscapularis tendon.
2. Previous shoulder surgery of any kind on the affected shoulder.
3. Total or partial rotator cuff rupture
4. Shoulder instability
5. Clinically verified acromioclavicular joint osteoarthritis
6. Patients who received no non-surgical treatment for their shoulder symptoms
7. Neurological symptoms or conditions (ie MS, Parkinson, CVA etc)
8. Injections in subacromial space in the previous three months.

9. Patients with psychosomatic complaints defined as a VAS-score for pain of * 90mm.
10. Patients with very mild shoulder pain, defined as a VAS-score < 30mm
11. Patients who report spontaneous improvement of their shoulder pain in the last days or weeks when their history is taken.
12. Patients not willing to consent or to return for follow up visits

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2010
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2010
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22357
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL30628.015.09
OMON	NL-OMON22357