Rotator Cuff Calcific Tendonitis: Needle US-guided treatment vs. Subacromial corticosteroids – A Randomized Controlled Trial.

No registrations found.

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

Summary

ID

NL-OMON25749

Source
Nationaal Trial Register

Brief title
RCCT-trial

Health condition

Rotator Cuff calcific tendonitis

Calcificerende tendinitis van de rotatoren manchet

Sponsors and support

Primary sponsor: Leiden University Medical Center, Leiden, the Netherlands

Rijnland Hospital, Leiderdorp, the Netherlands
Source(s) of monetary or material Support: ZonMW
Reumafonds

Intervention

Outcome measures

Primary outcome

Constant Shoulder Score (CS), measured at pre-intervention and at 6 weeks, 3 months, 6 months and 1 year after intervention.

Secondary outcome

Pre-intervention, and at 6 weeks, 3 months, 6 months and 1 year after treatment:

1. VAS-scores for pain during motion, pain at rest and shoulder function;

2. DASH-score;

3. RAND-36;

4. Western Ontario Rotator Cuff index.

Pre-intervention:

1. Demographic data (duration of symptoms, gender, age, BMI, sports/employment);

2. Calcific depositions and location of these depositions on radiographs of the shoulder: Gärtner-classification.

Immediately after intervention:

1. VAS-scores for pain during motion, pain at rest and shoulder function;

2. Barbotage Score form: Signs of bursitis, other shoulder injuries (impingement, acromioclavicular osteoarthritis, rotator cuff ruptures), substantion of the calcific depositions (hard, pulver, viscous), aspiration (yes/no), perforation (yes/no), location of calcific depostions.

Immediately after intervention, 6 weeks, and 1 year after intervention:

1. Presence of calcific depositions on standard radiographs (anteroposterior): Gärtner score.

Study description

Background summary

Calcifying tendinitis (CAT) of the shoulder is frequently diagnosed in case of shoulder complaints. It is a self-limiting disease, but there is much discussion about whether or not to treat CaT and which treatment methods can be applied.
Recently, in the “Medisch Contact” journal, it was stated that ultrasound-guided needle treatment for CaT (barbotage) is more effective than conservative treatment methods in patients diagnosed with CaT. This conclusion was based on a recent article of Serafini et al. in “Radiology”: a non-randomized trial in which patients were treated with barbotage in combination with subacromial corticosteroid injections. However, treatment and inclusion criteria of the control group were unclear.
A randomized controlled trial, in which both the patient and the control group are treated with subacromial corticosteroid injections, would provide more insight in the effectiveness of barbotage-treatment in patients with CaT.

Objective of the study:

To compare short (6 weeks, 3 months) and longer term (6 months, 1 year) results of ultrasound-guided barbotage treatment combined with subacromial corticosteroid injection treatment, versus ultrasound-guided treatment with subacromial corticosteroids injection, in patients with calcific tendonitis.

Study objective

We hypothesize that US-guided treatment (barbotage) in combination with corticosteroid injections gives better short-term clinical and radiographical results, compared to treatment with solely corticosteroid injections. Secondly, we expect that patients report more complaints in the first 2 weeks after US guided treatment. After one year of follow-up, we expect to find no differences between the two groups.

Study design

Pre-intervention, post-intervention, 6 weeks, 3 months, 6 months and 1 year.

Intervention

2 Usual care methods:

1. Group A: Ultrasound-guided barbotage treatment combined with subacromial corticosteroid injection;

2. Group B: Ultrasound-guided treatment with subacromial corticosteroid injection.

Contacts

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Eligibility criteria

Inclusion criteria

1. Calcifying tendonitis on x-rays (< 6 weeks before eventual inclusion);

2. Age: 18-65 years;

3. Diffuse lateral shoulder pain without improvement (> 3 months);

4. Referred to orthopedics or radiology department for treatment;

5. Pain at night or after activities;

6. Worsening of complaints with elevation or abduction of the arm.

Exclusion criteria

1. Comorbidities of the affected shoulder (with physical examination, X-rays, US). Subacromial impingement syndrome is not an exclusion criterium;

2. >1 subacromial corticosteroid injections <3 months before eventual exclusion;

3. Previous barbotage treatment of the affected shoulder;

4. History of trauma or surgery on the affected shoulder;

5. Instability of the shoulder;

6. Frozen shoulder (<90 degrees of external rotation when in 90 degrees of abduction);

7. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-04-2010
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	NL2158
NTR-old	NTR2282
Other	METC : P09.239
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A