

Rotator Cuff Calcific Tendonitis: Needle UltraSound-guided treatment vs. Subacromial corticosteroids: a randomized controlled trial

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32629

Source

ToetsingOnline

Brief title

RCCT

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

calcific deposits in the shoulder, tendinosis calcarea

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Reumafonds (+ ZonMW-AGIKO aangevraagd)

Intervention

Keyword: Barbotage, Calcifying tendinitis, Rotator cuff

Outcome measures

Primary outcome

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

- Constant Shoulder Score (CS).

Secondary outcome

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

- VAS-scores for pain during motion, pain at rest and shoulder function.
- DASH-score
- RAND-36.
- Western Ontario Rotator Cuff index

Pre-intervention:

- Demographic data (duration of symptoms, gender, age, BMI, sports/employment).
- Calcific depositions and location of these depositions on radiographs of the shoulder: Gärtner-classification.

Immediately after intervention:

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

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

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

- 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.

Study objective

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 calcificerende calcific.

Study design

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Randomized controlled trial, double blinded

Intervention

2 Usual care methods:

Group A: ultrasound-guided barbotage treatment combined with subacromial corticosteroid injection.

Group B: ultrasound-guided treatment with subacromial corticosteroid injection.

Study burden and risks

2 Usual care pathways are compared. In addition: randomization, 2 additional radiographs, filling out questionnaires and an additional follow-up visit.

--> Usual care--> no additional risks (low infection risk in both injection- and barbotage-treatment)

2 additional radiographs

Little additional risks compared to usual care, but the gaining of knowledge about frequently applied treatments of CaT. Furthermore, subjection to additional diagnostics and more contacts/visits to the doctor are a result of participation in the study.

Contacts

Public

Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL

Scientific

Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age: 18-65 years
- diffuse lateral shoulder pain without improvement (> 3 months)
- calcifying tendinitis on x-rays (< 6 weeks before eventual inclusion)
- referred to orthopedics or radiology department for treatment
- pain at night or after activities
- worsening of complaints with elevation or abduction of the arm

Exclusion criteria

- Comorbidities of the affected shoulder (with physical examination, X-rays, US). Subacromial impingement syndrome is not an exclusion criterium.
- >1 subacromial corticosteroid injections <3 months before eventual exclusion.
- previous barbotage treatment of the affected shoulder
- history of trauma or surgery on the affected shoulder
- instability of the shoulder
- frozen shoulder (<90 degrees of external rotation when in 90 degrees of abduction)
- no informed consent

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2010
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO	
Date:	16-02-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL30845.058.09