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),

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

- 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

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

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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

- Comoribidities 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