

# Follow-up of the Rotator Cuff Calcific Tendonitis trial:

## - Needle US-guided treatment vs. Subacromial corticosteroids -

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To compare the mid-term results (4-5 years) of ultrasound-guided barbotage combined with subacromial corticosteroid injections vs. ultrasound-guided subacromial corticosteroid injections alone, in patients with calcifying tendinitis, enrolled in the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON42504

### Source

ToetsingOnline

### Brief title

RCCT-2

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

calcifying tendonitis, shoulder calcific depositis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** sponsoring/fondsen via afd. Orthopaedie

## Intervention

**Keyword:** calcific tendonitis, rotator cuff, shoulder

## Outcome measures

### Primary outcome

Mid-term Constant Score (4-5 years).

### Secondary outcome

WORC, DASH, VAS scores for pain, anchor questions, aspect, location and classification (including Gärtner score) of eventual calcifications and the state of the rotator cuff (e.g. tendonitis or rupture y/n).

## Study description

### Background summary

Calcifying tendinitis (CAT) of the shoulder is frequently diagnosed in case of shoulder pain. CAT is generally considered to be a self-limiting condition, but symptoms can be very severe and long-lasting. Therefore, there is much debate on the treatment of CaT, and on the use of more or less invasive treatment methods.

In 2013, we published the results of a trial comparing two common treatments of CaT, with a follow-up period of 1 year (P09.239, Am J Sports Med 2013 Jul; 41 (7):. 1665-73): ultrasound-guided needling and lavage (barbotage) combined with subacromial corticosteroid injections vs. ultrasound-guided subacromial corticosteroid injections.

The results showed, that there was clinical and radiological progress in both treatment groups after 1 year of follow-up. However, both the clinical and radiological results of barbotage were significantly better.

This was the first trial in which these common treatment methods were compared. However, for both treatments, long-term results are unclear, as for most other treatments of CAT.

### Study objective

To compare the mid-term results (4-5 years) of ultrasound-guided barbotage

combined with subacromial corticosteroid injections vs. ultrasound-guided subacromial corticosteroid injections alone, in patients with calcifying tendinitis, enrolled in the RCCT trial in 2010-2011.

## Study design

Randomized controlled trial (RCT), double-blinded, mid-term results. Level of evidence: II.

## Study burden and risks

Participation in this study takes each subject 60 minutes of time. Subjects will undergo an X-ray (exposure to  $\pm 0.02$  mSv/X-ray-shoulder). Subjects will have no direct benefit from participating in this study.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Included in original RCCT trial (P09.239)

## Exclusion criteria

none

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2015
Enrollment:	48
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-11-2015
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	NL53922.058.15