

# Needling versus Radial Shockwave therapy in Calcific Tendinitis of the shoulder; a prospective randomised trial

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Purpose of this investigation is to establish which one of both treatments is most effective in resorption of the calcific deposit in the tendon and diminishing pain.

<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>	Interventional

## Summary

### ID

NL-OMON33563

### Source

ToetsingOnline

### Brief title

Needling vs Rswt in Calcific Tendinitis of the shoulder

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

Calcific tendinitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** HagaZiekenhuis

**Source(s) of monetary or material Support:** Financiering via Nederlands Reumafonds wordt aangevraagd / betaling uit eigen onderzoeksfonds

## Intervention

**Keyword:** Calcific, Needling, RSWT, Shoulder

## Outcome measures

### Primary outcome

Disappearance/ resorption of calcification in the rotator cuff muscles as seen on standard shoulder x-ray.

### Secondary outcome

Effect on pain and function, using VAS, Constant and Oxford shoulder score.

## Study description

### Background summary

Calcific tendinitis of the shoulder is a self-limiting disease of unknown origin in which calcium deposits are formed in the rotator cuff muscles. Most important symptoms are the deposition of a calcification in the tendon of the rotator cuff, pain and loss of function.

Needling and Radial Shockwave Therapy are both established treatments of calcific tendinitis, with well described effect on pain and resorption of the calcific deposit.

Which of these two is the better treatment is not known so far.

There are no studies which compare these two methods of treatment.

### Study objective

Purpose of this investigation is to establish which one of both treatments is most effective in resorption of the calcific deposit in the tendon and diminishing pain.

### Study design

Prospective (open) randomised controlled trial (RCT).

### Intervention

Needling or Radial Shockwave therapy.

## Study burden and risks

Needling: 15 minutes of treatment under local anaesthesia with lidocaine. At the end of the procedure, a deposit of corticosteroids is left behind.

RSWT: 4 sessions of 2500 impulses with an interval of a week:  
500 x 1.5 Bar at 4.5 Hz followed by 2000 x 2.5 Bar op 10 Hz.  
Efd 0.10 mJ/mm.  
Impuls time 2 ms

## Contacts

### Public

HagaZiekenhuis

Sportlaan 600  
2566 MJ Den Haag  
Nederland

### Scientific

HagaZiekenhuis

Sportlaan 600  
2566 MJ Den Haag  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Pain shoulder  
Calcification rotator cuff type I or II according to Gartner and Simons/ type I according to Patte and Goutallier  
Symptoms > 6 months  
VAS > 4 cm at time of evaluation  
failure of previous conservative treatments

## Exclusion criteria

Non dutch speaking  
Minor  
no informed consent  
rotator cuff tear, glenohumeral or acromioclavicular arthritis or acromioclavicular spur to rule out alternative explanations for the pain  
Pregnancy  
Implanted pacemaker  
Blood coagulation disorders or use of anticoagulant drugs;  
Inflammatory or neoplastic disorders  
Presence of type III (cloudy and transparent) calcifications according to the Gartner and Simons radiographic classification/type II according to Patte and Goutallier  
Conservative treatments administered in the last 2 weeks  
Participation in other medical trial

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2009

Enrollment: 40

Type: Actual

## Medical products/devices used

Generic name: Radial Shockwave Therapy  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 13-03-2009  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## 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	NL24917.098.08