Treatment of calcifying tendinitis of the shoulder: Us guided needling with corticosteroid injection vs. us guided corticosteroid injection alone, a randomized controlled trial.

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To compare long term outcome of patients with calcifying tendinitis of the rotator cuff treated with us guided needling with us guided cortocosteroids injection versus us guided cortocosteroids injection only. .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON37434

Source
ToetsingOnline

Brief title
Us guided needling vs. us guided corticosteroid injection alone.

Condition

- Tendon, ligament and cartilage disorders

Synonym
Calcifying tendinitis of the shoulder, shoulder calcifications

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Radiologische Diagnostiek

Intervention

Keyword: calcifying tendinitis, corticosteroid injection, needling, rotator cuff

Outcome measures

Primary outcome

To compare long term outcome of patients with calcifying tendinitis of the rotator cuff treated with us guided needling with us guided cortocosteroids injection versus us guided cortocosteroids injection only. The primary endpoint is VAS and Contstant scores at 1 year.

Secondary outcome

To get an insight in shoulder disability in daily life DASH score will be measured at baseline, 6 weeks, 3 months, 6 months and 1 year.

VAS and Constant score at baseline, 6 weeks, 3 and 6 months.

Sometimes patients have heavy pain very shortly after us guided needling. Vas score will be taken after two weeks.

The reaction of the calcifications of the rotator cuff tendons on the executed therapy will be measured on x-ray and ultrasound of the shoulder using Gärtner score on x-ray and a scoring system presented by Chiou et all. on ultrasound. The measurements will be made directly post-interventionial, at 6 weeks and one

year.

Study description

Background summary

Us guided needling is becoming an accepted treatment for patients with shoulder pain due to calcifying tendinitis. However, evidence for this treatment is lacking. We expect that patients treated with us guided needling with corticosteroid injection compared with patients treated with only corticosteroid injections have better clinical outcome after after one year follow-up.

Study objective

To compare long term outcome of patients with calcifying tendinitis of the rotator cuff treated with us guided needling with us guided cortocosteroids injection versus us guided cortocosteroids injection only. .

Study design

randomized controlled trial

Intervention

Us guided needling with us guided subacromial corticosteroid injection or us guided subacromial corticosteroid injection alone.

Study burden and risks

Both interventions are standard accepted therapies. There are no additional risks for patients included in this trial.

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

-Shoulder pain without improvement after 3 months despite conservative treatment
-Calcification on x-ray (Gärtner type I of II) and ultrasound in the supraspinatus tendon less than 6 weeks before the treatment
-All patients are first seen and included by the orthopaedic surgeon
-Last corticosteroid injection more than 3 months ago

Exclusion criteria

-Previous operation
- previous ultrasound guided needling of the shoulder
-Frozen shoulder
-Comorbidities of the painful shoulder on x-ray or ultrasound (ruptured tendon, fracture, bursitis,...)
-No informed consent
-Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2012
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Single-use Hypodermic-needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-03-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
ClinicalTrials.gov	NCT01538758
CCMO	NL38178.044.11