Needle aspiration of calcific deposits versus Shock Wave Therapy for conservative therapy resistant calcifying tendinitis of the shoulder. A Randomized Controlled Trial

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

Summary

ID

NL-OMON49558

Source
ToetsingOnline

Brief title
NACD vs ESWT for calcifying tendinitis van de schouder

Condition

- Tendon, ligament and cartilage disorders

Synonym
Calcific tendinitis of the shoulder; calcific deposits

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Cooperatie Orthopedie

Intervention

Keyword: calcifying tendinitis, ESWT, NACD, RCT

Outcome measures

Primary outcome

The primary outcome will be the between group differences in functional outcome (measured with the Constant-Murley Score) between baseline and 12 months follow-up.

Secondary outcome

1. to assess the cost-effectiveness of both interventions over a period of 12 months.

2. to assess between group differences in change in pain scores, quality of life, adverse events and use of medications between baseline and 12 months follow-up.

Study description

Background summary

Calcific tendinitis of the shoulder is a common disorder with a huge disease burden. The initial treatment choice is non-operatively, including anti-inflammatory drugs, ice-therapy, physiotherapy and/or corticosteroid injection. If non-operative treatment is not successful to relieve the symptoms, surgery is often the next step treatment. However, new treatment modalities have emerged, namely focused extracorporeal shockwave therapy (ESWT) and needle aspiration of the calcific deposits (NACD). Both modalities have shown promising results. Till date, there are no studies available which compare the effectiveness of both new treatment modalities. Consequently, it is

not clear what the most (cost-)effective treatment option is for patients with calcifying tendinitis who do not respond to non-operative treatment.

Study objective

Our primary objective is to compare the effectiveness of ESWT and NACD for patients with calcifying tendinitis of the shoulder. Our hypothesis is superiority of ESWT or NACD above the other treatment in functional recovery over a period of 12 months will be found. (superiority design)Secondary objective is to compare the cost-effectiveness of both treatment options.

Study design

An open-labeled randomized, controlled trial.

Intervention

Patients will be randomized to receive ESWT or NACD treatment. ESWT treatment: patients will receive a focused ESWT. NACD treatment: a sonographically guided removal of the calcific deposits will be performed. Both will be conducted according to a standardized protocol, as currently used in Máxima MC.

Study burden and risks

Both interventions are currently used as a part of usual care by orthopedic surgeons of Máxima MC for the target population. Both interventions have limited risk (less than 1%) on adverse events. Some patients report a contemporary increase in pain a few weeks after treatment. This results from the inflammatory response to reabsorb the calcific deposits. This usually resolves spontaneously within a few weeks. As with all (minimal) invasive treatments there is a chance of an infection, however this percentage in low and the same in the two treatment groups. The treatment specific reported adverse events are minor and temporarily (bruises with ESWT). The patients that will participate in the current study will have no additional risk compared to the those patients that are not willing to participate, since the treatments are part of usual care. Patients will be informed about the known potential risks of both interventions. Of the participating patients two additional outpatient clinic visits at 8 weeks and 12 months follow-up will be asked. During this visits additional radiographs will be made. Besides patients will be asked to fill in questionnaires (web-based, by email).

Contacts

Public

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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 years
• calcifications on conventional x-rays
O type I and II calcifications according to the Gärtner classification.
O minimal diameter 10 mm on AP view
• able and willing to comply to study protocol

Exclusion criteria

* clinical signs of a frozen shoulder or adhesive capsulitis
• operations of the affected shoulder in medical history
* ESWT or NACD tretament during the last 6 months
• full-thickness lesion of the rotator cuff tendon(s) on sonography
• clinical and radiological signs of acute subacromial bursitis
• clinical and radiological signs of acromioclavicular osteoarthritis
• Rheumatic Arthritis or fibromyalgia

• any contra-indications for the specific treatments (e.g. coagulopathies, malignancies in treated area)
• other intra articular pathology: cartilage lesions, biceps pathology.

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):	24-05-2018
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-03-2019
Application type:	Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25891
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60762.015.17
OMON	NL-OMON25891