NECST study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON25891

Source
NTR

Brief title
NECST study

Condition

- Muscle disorders

Health condition

calcifying tendinitis shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Màxima Medical Centre
Source(s) of monetary or material Support: Màxima Medical Centre

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Between group difference in recovery of functional outcome score of the CMS between baseline and 12 months follow-up

Secondary outcome

Between group differences in change in pain scores, quality of life, adverse events and use of medications. Also cost-effectiveness will be analyzed to be able to analyze this parts of the iPCQ and ProDisq must be completed. Furthermore, the ‘Diagnose & Behandel Combinatie (DBC)’ will be examined two find a difference in the procedural costs of the two treatment modalities

Study description

Background summary

Calcifying tendinitis (CT) of the shoulder is a common disease in which calcium particles are deposited in one or more tendons of the rotator cuff. This can result in a typical pattern of pain, impairments in daily living and decreased range of motion. In a patient with shoulder complaints the incidence of CT is reported as high as 54%. This disease mainly affects individuals between 30 and 60 years of age. Males and females are thought to be equally affected.(1-5,8) There is very limited evidence available about the cost-effectiveness of any intervention of CT of shoulder. Only Haake et al(18) published results concerning the cost-effectiveness. They found that ESWT costs EUR 1.750 to EUR 3.500 as a results of being unfit to work. The etiology of CT of the rotator cuff is still a matter of dispute. It has been suggested that it is related to a locally decreased oxygen tension or hypoxia.(2)

The treatment consists at first conservative measures such as anti-inflammatory drugs, ice-therapy, physical therapy and/or corticosteroid injections.(2,10,11, 17) When this fails next step treatment must be considered. New treatment modalities have emerged. Needle aspiration of the calcific deposits (NACD) and focused extracorporeal shockwave therapy (ESWT) are proven to be effective therapeutic options. NACD has shown promising results, mainly in non-comparing studies.(2) However, ESWT also shows promising results and focused ESWT has been proven to be the more effective then radial ESWT.(19) Although in the existing orthopedic literature both treatment methods seem to be viable, comparative

studies are not available yet. Therefore, the exact place in the treatment algorithm of CT is not clear yet.(17) The aim of the current study is to compare the functional and clinical outcome of the aforementioned treatment options on the short and midterm in a randomized trial. A secondary aim is to compare the cost-effectiveness.

Study objective

Our primary objective is to compare the effectiveness of NACD and ESWT for patients with calcifying tendinitis of the shoulder. Our hypothesis is superiority of NACD or ESWT 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

T0 = start of study

T1 = 8 weeks post-intervention

T2 = 6 months post-intervention

T3 = 12 months post-intervention

Intervention

focused extracorporeal shockwave therapy

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- age: >18 years

- chronic shoulder complaints (> 6 months)

- calcifications on conventional x-rays O type I en II calcifications according to the Gärtner classification O minimal diameter of calcification of 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 history

- ESWT or NACD treatment during the last 6 months

- clinical and radiological signs of acute subacromial bursitis

- full-thickness lesion of the rotator cuff tendon(s) on sonography

- clinical and radiological signs of acromioclavicular osteoarthritis

- Rheumatic Arthritis or fibromyalgia

- other intra articular pathology: cartilage lesions, biceps pathology

- any contra-indication for the specific treatments (e.g. coagulopathies, malignancies in treated area)..

Study design

Design

Study phase:	N/A
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:	0
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	16-02-2018
Application type:	Not applicable
Review commission:	METC Máxima Medisch Centrum

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Study registrations

Followed up by the following (possibly more current) registration

ID: 49558
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5527
NTR-old	NTR7093
CCMO	NL60762.015.17
OMON	NL-OMON49558

Study results