NECST studie

Gepubliceerd: 11-03-2018 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Spieraandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25891

Bron
Nationaal Trial Register

Verkorte titel
NECST study

Aandoening

- Spieraandoeningen

Aandoening

calcifying tendinitis shoulder

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Màxima Medical Centre
Overige ondersteuning: Màxima Medical Centre

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0 = start of study

T1 = 8 weeks post-intervention

T2 = 6 months post-intervention

T3 = 12 months post-intervention

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)

Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)..

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-05-2018
Aantal proefpersonen:	0
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	16-02-2018
Soort:	Niet van toepassing
Toetsingscommissie:	METC Máxima Medisch Centrum

Postbus 7777
5500 MB Veldhoven
040 888 9528
metc@mmc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49558
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten