Rotator Cuff Calcific Tendonitis: Needle US-guided treatment vs. Subacromial corticosteroids – A Randomized Controlled Trial.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25749

Bron
Nationaal Trial Register

Verkorte titel
RCCT-trial

Aandoening

Rotator Cuff calcific tendonitis

Calcificerende tendinitis van de rotatoren manchet

Ondersteuning

Primaire sponsor: Leiden University Medical Center, Leiden, the Netherlands

Rijnland Hospital, Leiderdorp, the Netherlands
Overige ondersteuning: ZonMW

Reumafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Constant Shoulder Score (CS), measured at pre-intervention and at 6 weeks, 3 months, 6 months and 1 year after intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Calcifying tendinitis (CAT) of the shoulder is frequently diagnosed in case of shoulder complaints. It is a self-limiting disease, but there is much discussion about whether or not to treat CaT and which treatment methods can be applied.
Recently, in the “Medisch Contact” journal, it was stated that ultrasound-guided needle treatment for CaT (barbotage) is more effective than conservative treatment methods in patients diagnosed with CaT. This conclusion was based on a recent article of Serafini et al. in “Radiology”: a non-randomized trial in which patients were treated with barbotage in combination with subacromial corticosteroid injections. However, treatment and inclusion criteria of the control group were unclear.
A randomized controlled trial, in which both the patient and the control group are treated with subacromial corticosteroid injections, would provide more insight in the effectiveness of barbotage-treatment in patients with CaT.

Objective of the study:

To compare short (6 weeks, 3 months) and longer term (6 months, 1 year) results of ultrasound-guided barbotage treatment combined with subacromial corticosteroid injection treatment, versus ultrasound-guided treatment with subacromial corticosteroids injection, in patients with calcific tendonitis.

Doel van het onderzoek

We hypothesize that US-guided treatment (barbotage) in combination with corticosteroid injections gives better short-term clinical and radiographical results, compared to treatment with solely corticosteroid injections. Secondly, we expect that patients report more complaints in the first 2 weeks after US guided treatment. After one year of follow-up, we

expect to find no differences between the two groups.

Onderzoeksopzet

Pre-intervention, post-intervention, 6 weeks, 3 months, 6 months and 1 year.

Onderzoeksproduct en/of interventie

2 Usual care methods:

1. Group A: Ultrasound-guided barbotage treatment combined with subacromial corticosteroid injection;

2. Group B: Ultrasound-guided treatment with subacromial corticosteroid injection.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Calcifying tendonitis on x-rays (< 6 weeks before eventual inclusion);

2. Age: 18-65 years;

3. Diffuse lateral shoulder pain without improvement (> 3 months);

4. Referred to orthopedics or radiology department for treatment;

5. Pain at night or after activities;

6. Worsening of complaints with elevation or abduction of the arm.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Comorbidities of the affected shoulder (with physical examination, X-rays, US). Subacromial impingement syndrome is not an exclusion criterium;

2. >1 subacromial corticosteroid injections <3 months before eventual exclusion;

3. Previous barbotage treatment of the affected shoulder;

4. History of trauma or surgery on the affected shoulder;

5. Instability of the shoulder;

6. Frozen shoulder (<90 degrees of external rotation when in 90 degrees of abduction);

7. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-02-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-04-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2158
NTR-old	NTR2282
Ander register	METC : P09.239
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A