Verkalkende tendinitis van de schouder: Is er een te prefereren chirurgische behandeling?

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Our hypothesis is that all three surgical treatments (Arthroscopic Neer, Arthroscopic debridement of calcifications or Arthroscopic Neer + debridement of calcifications) will lead to a significant pain reduction and all three surgical procedures...

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

Samenvatting

ID

NL-OMON24524

Bron
NTR

Verkorte titel
calcifying, tendinitis, surgical treatment, randomized controlled trial

Aandoening

Our study population will include patients with chronic (>6 months) shoulder complaints with calcifications visible on conventional x-rays and not responded to conservative therapy

Ondersteuning

Primaire sponsor: Dr. E.J.P Jansen, investigator initiated, with a financial sponsor
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

6.2.1 VAS for pain
This pain score indicates on a scale from 1 till 100 their pain level. In this scale 1 is minor pain and 100 is the worst pain they ever experienced.

Toelichting onderzoek

Achtergrond van het onderzoek

Calcifying tendinitis of the shoulder is a common disorder and has a large disease burden. The disease is first treated conservatively, including anti-inflammatory drugs, ice-therapy, physiotherapy, corticosteroid injections, extracorporeal shock wave therapy (ESWT) and/or needling. After a failed conservative treatment, surgery is often the next step treatment. However, there is no consensus about whether there is an preferred surgical procedure. Several studies have investigated different surgical procedures separately, but there are not any comparing studies available in current literature, especially no Randomized Controlled Trial (RCT). There are three main surgical procedures to treat calcifying tendinitis of the shoulder: The first one is to perform an acromioplasty according to Neer (including the removal of the anterior edge and undersurface of the anterior part of the acromion with the attached coraco-acromial ligament in combination with a bursectomy); The second procedure is the same acromioplasty but in combination with debridement of the calcification; The last procedure is to solely debride the calcifications without an acromioplasty.

Doel van het onderzoek

Our hypothesis is that all three surgical treatments (Arthroscopic Neer, Arthroscopic debridement of calcifications or Arthroscopic Neer + debridement of calcifications) will lead to a significant pain reduction and all three surgical procedures shows to the same reduction, both in the short term (6 weeks, ± 1 week) and in the midterm (6 months, ± 2 weeks).

Onderzoeksopzet

•Start T=0 (>6 months of conservative treatment)

•6 weeks post-operatively

•6 months post-operatively

Onderzoeksproduct en/of interventie

There are three main surgical procedures of calcifying tendinitis of the shoulder. The first one is to perform an acromioplasty according to Neer (including the removal of the anterior edge and undersurface of the anterior part of the acromion with the attached coraco-acromial ligament in combination with a bursectomy). The second procedure is the same acromioplasty but then in combination with debridement of the calcifications. This

debridement will be done by localizing the calcifications by needling during shoulder arthroscopy, when the calcification is localized it will be debrided using a shaver and extensive rinsing. The last procedure is to solely debride the calcifications without an acromioplasty.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•Age: 30-60 years

•Full range of motion of the affected shoulder (>120o abduction and anteflexion, unrestricted external rotation of >80o)

•Calcifications on the x-rays

o Type I and II calcifications according to the Gärtner classification (chapter 4.1.3)

oMinimal diameter of 5 mm on AP view

•Unsuccessful conservative therapy for at least 6 months

•Ability and willingness to fill out the necessary questionnaires

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•Clinical signs of a frozen shoulder or adhesive capsulitis

•Operations of the affected shoulder in personal medical history

•Clinical and radiologic signs of full-thickness lesion of, one of, the rotator cuff tendons.

•Clinical and radiologic signs of acromioclavicular osteoarthritis

•History of rheumatic arthritis or fibromyalgia

•Type III calcifications according to the Gärtner classification

•Not able or willing to participate in this trial

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	114
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-01-2015
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	NL4947
NTR-old	NTR5051
Ander register	NL50468.096.14, CCMO : 14-T-112, METC

Resultaten

Samenvatting resultaten
NA