ESWT vs Barbotage

Gepubliceerd: 25-02-2014 Laatst bijgewerkt: 18-08-2022

Primary Objective: The primary objective of this study is to evaluate the difference in functional outcome, measured by the Constant Murley Scale at six weeks, three months, six months and one year, after treatment with high-energy ESWT versus US-...

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

Samenvatting

ID

NL-OMON24831

Bron
NTR

Verkorte titel
KALK

Aandoening

shoulder, rotator cuff, calcific, tendinopathy, treatment, shockwave, ESWT, barbotage, percutaneous needling, minimally invasive, schouder, tendinosis calcarea

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: Stimuleringsfonds Spaarne Ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Constant Murley Score

Toelichting onderzoek

Achtergrond van het onderzoek

In this randomized clinical trial patients with chronic calcific tendinopathy, not responding to a conservative treatment, will be allocated to either treatment with US-guided needling of high-energy shockwave therapy.

Doel van het onderzoek

Primary Objective:
The primary objective of this study is to evaluate the difference in functional outcome, measured by the Constant Murley Scale at six weeks, three months, six months and one year, after treatment with high-energy ESWT versus US-guided double needle percutaneous barbotage for calcific tendinopathy of the rotator cuff.

Secondary Objective(s):
The secondary objective is to evaluate the difference in the secondary outcome measures after treatment with high-energy ESWT versus US-guided double needle percutaneous barbotage for calcific tendinopathy of the rotator cuff.

Secondary outcome measures
VAS (pain) scale
VAS (satisfaction) scale
SF-12
Work ability questionnaire
DASH
The presence and size of calcific deposits on conventional radiography

Onderzoeksopzet

Follow-up: 6 wk, 3m, 6m, 1 year

Onderzoeksproduct en/of interventie

High-energy Extracorporeal Shockwave therapie (ESWT)
Ultrasound guided double percutaneous needling (Barbotage)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age > 18
Clinical signs of subacromial pain of the Symptoms persisting for more than four Unsuccessful conservative therapy within the previous four months (Physiotherapy, radiotherapy, infiltration with local anaesthetics and/or steroids, anti-inflammatory drugs.)
Standardised radiographs showing calcific deposits with a diameter of at least 5 mm
o Morphological type-I and type-II deposits corresponding to the classification of Gartner and Simons on radiographs: Type I, sharply outlined and densely structured. Type II, sharply outlined and inhomogenous or homogenous with no defined border

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Evidence of full thickness tears of the rotator cuff on physical examination, ultrasound images or MRI
Radiological signs of spontaneous resorption of the deposit and type-III deposits according to the classification of Gartner and Simons: Type III, cloudy and transparent in structure
Calcific deposits in multiple tendons of the rotator cuff

Acute subacromial/subdeltoid bursitis
Osteoarthritis of the glenohumeral or acromioclavicular joint
Adhesive capsulitis
Previous surgery to the shoulder
Instability of the shoulder
ESWT / barbotage within the last year
Reumatoid arthritis
Neurological disorders or dysfunction of the upper limb
Heart pacemaker, pregnancy, infection, tumour, hypocoagulability
Unability to give informed consent

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-02-2014
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	NL4303
NTR-old	NTR4448
Ander register	NL44205.094.13 : M013-014

Resultaten