Debridement vs debridement and biodegradable balloon

Gepubliceerd: 28-06-2018 Laatst bijgewerkt: 30-11-2024

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

Samenvatting

ID

NL-OMON24952

Bron
NTR

Aandoening

Shoulder debridement biodegradable balloon rotator cuff tear Schouder debridement , bio-oplosbare ballon, rotator cuff herstel

Ondersteuning

Primaire sponsor: Afdeling Orthopaedie
HAGA Hospital
Sportlaan 600
2566MJ, Den Haag, Nederland

Overige ondersteuning: Zelf gefinancierde studie:

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Is there a minimal clinical difference (NRS >2) in pain levels between subjects receiving an arthroscopic debridement with a subacromial bio-absorbable Balloon and solely arthroscopic debridement in subjects with symptomatic irreparable cuff tears after 1 year.

Toelichting onderzoek

Onderzoeksopzet

Subjects are measured preoperative, 3 and 10 weeks postoperative, 6, 12 months and 5 years postoperative

Onderzoeksproduct en/of interventie

Group 1 Arthroscopic debridement

Group 2 Arthroscopic debridement with implantation of a bio-absorbable Balloon

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Subject has an irreparable supra- and infraspinatus tendon tear confirmed by ultrasound or

MRI and is according to the Orthopaedic Surgeon a suitable candidate for debridement.

• The symptoms of the subjects are existing for at least twelve months, despite conservative treatment, including physiotherapy, subacromial infiltration with corticosteroids or anti-inflammatory drugs.

• Subjects are older than 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Subject is not able to complete the daily questionnaires in Dutch.

• Subject, in the opinion of the investigator, is not able to understand this investigation and is not willing and able to perform all study procedures and co-operate with investigational procedures.

• Subject has glenohumeral osteo-arthrosis grade 3 and 4 (KELLGREN and LAWRENCE 494-502).

• Subject has a total subscalpularis tendon tear.

• Subject, in the opinion of the Investigator, is a drug or alcohol abuser (in the last 5 years) or has a psychological disorder that could affect their ability to complete subject reported questionnaires or be compliant with follow-up requirements.

• Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.

• Subject has an active elevation of less than 60 degrees (pseudoparalysis).

• Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three months.

• Subject is allergic to the Balloon material

• Subject has a medical condition with less than 3 years of life expectancy.

• Subject has refused voluntary, written informed consent to participate in this randomized controlled trial.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-01-2017
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50270
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7112
NTR-old	NTR7317
CCMO	NL58522.098.16
OMON	NL-OMON50270

Resultaten