Functional and radiological outcome of non-surgical vs surgical treatment for the atraumatic cuff rupture after 1 year (COPACABANA trial).

Gepubliceerd: 27-05-2010 Laatst bijgewerkt: 18-08-2022

Comparison between surgical vs non surgical treatment of an atraumatic cuff rupture.

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

Samenvatting

ID

NL-OMON26949

Bron
Nationaal Trial Register

Verkorte titel
COPACABANA

Aandoening

atraumatic (atraumatisch)
rotator cuff rupture (rotator cuff ruptuur)
subacromial impingement syndrome (impingement syndroom)
shoulder (schouder)

Ondersteuning

Primaire sponsor: UMCG
Martini Hospital Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Functional outcome is the primary outcome measurement. The Constant Murley Score will be used. This score system combines a shoulder function test (65 points) with a subjective evaluation of complaints by the patient (35 points). The Constant Murley Score is a valid score for shoulder function and rotator cuff ruptures and repairs.

Toelichting onderzoek

Achtergrond van het onderzoek

Tendinous degeneration of the rotator cuff of the shoulder is a frequently observed disorder. With subsequent atraumatic rotator cuff tendon rupture it can give rise to long lasting symptoms and impairment, although degenerative ruptures are also observed in asymptomatic elderly individuals. Treatment can be non-surgically or surgically. Reasonable results are reported from both treatment modalities. No studies of quality are performed to compare these treatment modalities.

The objective of this study is whether there is an difference in outcome between surgical repair and non-surgical treatment of an atraumatic rotator cuff tendon rupture.

A randomized controlled trial will be conducted. Patients, aged between 45 and 75 years with an atraumatic rotator cuff tendon rupture as diagnosed on MRI will be included. Exclusion criteria are traumatic rotator cuff tendon rupture, frozen shoulder, diabetes mellitus. Patients are randomized in two groups. The non-surgical treatment consists of physical therapy, acoording to a standardised format, NSAID’s and if indicated subacromial infiltration of local anesthetic and corticosteroids. Surgical therapy is conducted under general or regional anesthesia. An acromioplasty with repair of the rotator cuff tendon will be performed, in a standardized way.

Follow-up visits will take place after 6 weeks, 3 months, 6 months and 1 year postoperatively. One year postoperatively a second MRI will be performed of all patients.

At all measurement points, the Constant score will be assessed. Secondary outcome measures are the Dutch simple shoulder score, a visual analogue scale for pain and impairment, the Goutaillier score which defines fatty degeneration of the rotator cuff, and measurements of the anatomical location of the rotator cuff rupture, integrity of the rotator cuff and economic evaluation.

Discussion:

In current practice both treatments are being performed. There is a lack of studies of good quality which compare surgical vs. non-surgical treatment of rotator cuff tendon rupture. This randomized controlled trial has been designed to determine whether the surgical treatment of a rotator cuff tendon rupture gives a better functional outcome than non-surgical treatment.

Doel van het onderzoek

Comparison between surgical vs non surgical treatment of an atraumatic cuff rupture.

Onderzoeksopzet

Follow-up on both groups will take place at 6 weeks, 3, 6 and 12 months after commencement of treatment. At 12 months follow up a second MRI of the affected shoulder will be performed.

Onderzoeksproduct en/of interventie

1. 54 patients are randomized for acromioplasty with surgical repair of rotator cuff;

2. 54 patients are randomized for conservative therapy consisting of physical therapy, subacromial infiltration with local analgesic and corticosteroids, analgesic medication, for example NSAID’s.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In all patients referred to the department of Orthopaedic surgery and Rehabilitation of both the Martini Hospital and the University Medical Centre in Groningen, aged between 45 en 75 years, with a clinically suspected atraumatic rotator cuff rupture a MRI scan will be performed. If on the MRI of the affected shoulder 2 independent assessors diagnose a full thickness rotator cuff rupture with degenerative characteristics, the patient will be included in this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are traumatic rotator cuff rupture, no signs of degeneration on MRI, previous surgical treatment of the shoulder, frozen shoulder, radiological and symptomatic osteoarthritis of the gleno-humeral or acromio-clavicular joint, (rheumatoid) arthritis, diabetes mellitus and cognitive disorders, neurological disease or language barriers impairing participation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2010
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	NL2218
NTR-old	NTR2343
Ander register	METC UMCG : 2008/040
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A