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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26949

Source
Nationaal Trial Register

Brief title
COPACABANA

Health condition

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

Sponsors and support

Primary sponsor: UMCG
Martini Hospital Groningen

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome measurements are the Dutch Simple Shoulder Test, the Visual Analog Scale for pain and restriction, the Goutallier score, anatomical localization of the rotator cuff rupture, integrity of the rotator cuff and economic evaluation.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

Contacts

Public
PO Box 30.033
F.O. Lambers Heerspink
van Swietenplein 1
Groningen 9700 RM
The Netherlands
+31 (0)50 5247723
Scientific

PO Box 30.033
F.O. Lambers Heerspink
van Swietenplein 1
Groningen 9700 RM
The Netherlands
+31 (0)50 5247723

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	108
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-05-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2218
NTR-old	NTR2343
Other	METC UMCG : 2008/040
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A