Cost-effectiveness of biceps tenotomy with or without cuff repair in patients with stage 2-3 Goutallier fatty degenerative cuff lesions. A randomized controlled multicenter trial.

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this multicentre randomized controlled non-inferiority trial is designed to compare the short and long term outcome of patients who underwent an arthroscopic tenotomy of the long head of the biceps tendon with or without a cuff repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON47699

Source
ToetsingOnline

Brief title
Biceps tenotomy with or without cuff repair

Condition

- Tendon, ligament and cartilage disorders

Synonym
Rototor cuff lesion; shoulder lesion

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Rotator cuff lesion, Shoulder, Tenotomy

Outcome measures

Primary outcome

The primary parameter is the rotator cuff specific quality of life (Western

Ontario Rotator Cuff index)) on the short term (6 months after surgery).

Secondary outcome

Secondary parameters are quality of life at 1 year after surgery and function

(glenohumeral range of motion, Constant-Murley Score), recovery status, pain

(Visual Analogue Scale), economic evaluation, satisfaction of treatment on the

short and long term and re-tear rate at 6 months determined with an ultrasound.

Study description

Background summary

For patients who are diagnosed with lesions of the rotator cuff that present advanced levels of fatty degeneration, arthroscopic repair of the rotator cuff remains controversial despite several case series demonstrating significant clinical improvement in this patient category. This controversy can be attributed to the frequently reported high failure rate of the tendon fixation and the fact that it remains unclear why repair for these tears result in significant clinical improvement independent of the occurrence of such a re-tear. Recent publications have reported comparable clinical improvements when merely a tenotomy or tenodesis of the long head of the biceps tendon was performed and the rotator cuff tear was left untreated. These observations raise questions on the value of performing the more extensive and therefore expensive cuff repairs in degenerative cuff tears. Even more, rehabilitation after an isolated tenotomy is much less cumbersome as compared to

rehabilitation after rotator cuff repair and, therefore, might result in improved patient satisfaction. Therefore, the goal of this trial is to study the short term difference in function and quality of life between patients undergoing arthroscopic cuff repair with an additional bicepstenotomy or an isolated bicepstenotomy and to include an economic evaluation.

Study objective

this multicentre randomized controlled non-inferiority trial is designed to compare the short and long term outcome of patients who underwent an arthroscopic tenotomy of the long head of the biceps tendon with or without a cuff repair.

Study design

This study will be a randomized (1:1 ratio) controlled trial, including an economic evaluation. Due to the obvious differences in post-operative rehabilitation protocols, patients, surgeons and researchers will not be blinded for treatment.

Intervention

One group which will undergo biceps tenotomy without cuff repair (N=86) and the other group will undergo biceps tenotomy with repair of the rotator cuff (N=86). Postoperative rehabilitation will be directly functional for the patients receiving isolated tenotomy of the long head of the biceps tendon (patients are allowed to use an antalgic shoulder-immobilizer) and 6 weeks of immobilization for patients who underwent a tenotomy with a cuff repair.

Study burden and risks

The current standard treatment for this specific patient group is subject of debate and at this time depends mostly on the preference of the orthopaedic surgeon varying from a conservative treatment (physiotherapy, subacromial corticosteriod infiltration, use of analgesia), an arthroscopic bicepstenotomy is performed with or without a cuff repair, or implantation of a reversed shoulder prosthesis. In this study, patients will undergo bicepstenotomy with or without cuff repair. Both treatments are accepted procedures and within our study population indicated surgical options. Therefore this study does not involve additional risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* *60 years of age
* Willing and able to comply with the study protocol
* Signed informed consent
* Cuff lesion, involving the supraspinatus and or infraspinatus tendon, with at least one of the involved tendons having stage 2-3 Goutallier fatty infiltration
* Peroperative pathologic involvement of the long head of the biceps tendon. Including: (minor signs of) degeneration, or signs of inflammation, or instability (subluxation or dislocation), or traumatic (partial tear, SLAP (Superior Labrum from Anterior to Posterior) lesions)
* History of shoulder complaints > 6 months suggestive for a degenerative rotator cuff with or without non-significant preceding trauma
* Sufficient understanding of the Dutch language

Exclusion criteria

* Cuff arthropathy according Hamada classification > grade 2
* Pseudoparalysis
* Full subscapularis tendon tear (delamination or partial avulsion accepted)
* Injury of the teres minor tendon
* Peroperative fully healthy macroscopic aspect of the long head of the biceps tendon
* Mainly complaints from an arthrotic acromioclavicular joint and less from a subacromial origin, determined clinically or by subacromial/acromioclavicular infiltration (acromioclavicular joint resection is not an exclusion criteria)
* Shoulder instability for which labral repair is indicated
* Irreparable rotator cuff tear, based on MRI and peroperative findings
* Unsuccessful surgery in the affected shoulder in history or surgery in the affected shoulder < 1 year ago
* Previous rotator cuff repair on the ipsilateral shoulder.
* Ipsilateral neurological pathology possibly affecting functional outcome
* Full tear of the biceps tendon
* Cervical spine pathology affecting the functional outcome
* Body Mass Index (BMI) > 35 kg/m²
* Time between surgery and MRI > 6 months
* Fracture of the humeral head involved in the cuff tear
* MRI not performed preoperative

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2018

Enrollment:	172
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26658
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL54313.100.15
OMON	NL-OMON26658