

Een gerandomiseerde studie tussen twee typen peesomleggingen als behandeling voor zeer grote scheuren in de schouderpezen

No registrations found.

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

Summary

ID

NL-OMON19939

Source

Nationaal Trial Register

Brief title

Tesla

Health condition

rotator cuff tear
massive rotator cuff tear
shoulder complaints
rotator cuff pathology

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Constant score at 1 year postoperatively

Secondary outcome

Constant score at 3 and 6 months postoperatively.

At 3,6 and 12 months postoperatively.

Range of motion using a goniometer and an electromagnetic tracking device.

EMG activity of various shoulder muscles.

Visual analogue scale for pain.

Complications

Re-operations or other interventions.

SF-12

DASH

WORC

Study description

Study objective

Teres Major muscle transfer group will show significant better improvement in active abduction and external rotation than the LD group after 1 year.

Study design

3-6 and 12 months postoperatively

Intervention

Teres major muscle transfer versus latissimus dorsi muscle transfer

The patient is positioned in lateral position on the unaffected side. The first skin incision runs just above the posterior pillar of the armpit. The muscle of interest is identified, transversing under the medial head of the triceps.

dorsi. The axillary and radial nerves are identified above and below the tendon insertion.

The tendon is detached from the humerus. The second skin incision is made lateral from the acromion process (deltoid split approach). The deltoid is split and the subdeltoid bursa opened. The rotator cuff is examined. The tendon is passed under the posterior part of the deltoid muscle to the subacromial space. The tendon is inserted in the m. infraspinatus area using one or two bone-anchors.

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients suffering MRI proven massive RC tears. A massive Rotator Cuff tear is defined as a type III tear according to Davidson et al. Retraction grade II or III according to Patte and Grade >II fatty infiltration.

2) Invalidating pain of the affected shoulder

3) Functional deficit (loss of external rotation and/or abduction)

Exclusion criteria

- Tear of the m. subscapularis
- Radiographic osteoarthritis of the glenohumeral joint of Kellgren > grade 2 and/or acromioclavicular joint and/or sternoclavicular joint
- History of fractures or dislocation of the shoulder
- Tumors
- No informed consent
- Insufficient Dutch Language skills
- Age <18 years and >80
- Contra-indications for surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date: 05-08-2014

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	NL4580
NTR-old	NTR4721
Other	37838 CCMO : P11.183 METC LUMC

Study results