Muscle Tendon Transfers for Massive Rotator Cuff Tears: Midterm follow-up

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

Summary

ID

NL-OMON37726

Source
ToetsingOnline

Brief title
MuTraROC

Condition

- Tendon, ligament and cartilage disorders

Synonym
latissimus dorsi transfer, muscle transfer, teres major transfer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: latissimus dorsi, rotator cuff, schouder, teres major, transposition

Outcome measures

Primary outcome

The main study parameter is the Constant score (CS), pre-operative and minimal

2 years postoperative.

Secondary outcome

Secondary parameters are RoM, VAS, SF-12, DASH and WORC.

Study description

Background summary

Several types of muscle tendon transfers have been described in literature as a salvage procedure for irreparable posterior-superior massive RC tears, two of these treatment options have been adopted in our hospital: the m. teres major (TM) transfer and m. latissimus dorsi (LD) transfer. Which tendon transfer results in the best functional outcome remains controversial. One or the other might have better functional improvements of might have potential disadvantages. In an analysis of muscle function, the TM transfer proved to be successful. Yet no long-term clinical outcome results have been reported for the TM transfer. Midterm outcome of LD transfer are relatively favourable, however reported for variable indications in small research groups.
In this project we will evaluate the potential (dis)advantages of the two transfers at midterm follow-up.
Our first hypothesis is that at follow-up, the Range of Motion (RoM) will be increased in both patient groups versus the pre-operative status. Our second hypothesis is that the TM transfer group and LD group will show significant improvement in active abduction and external rotation; this will lead to significant increase in quality of life.

Study objective

The study is primarily designed to discribe the clinical outcome at mid-term follow-up in respect to the baseline of the TM transfer and the LD transfer in patients with a massive posterior-superior rotator cuff tear. Our secondary objective is to asses the quality of life in these patients, which received

either a TM transfer or a LD transfer.

Study design

Retrospective cohort study with two historical patient groups: one group received a TM transfer (2003-2007) and the other group received a LD transfer (2007-2009).

Study burden and risks

The potential risk associated with this study is negligible. While the subjects participating in this study may not directly derive any immediate benefits, the results of this study should improve the understanding of which muscle in which patients* type is best to transfer. This information will be extremely useful in optimizing treatment of irreparable massive RC tears, and improving long-term results. Further treatment and rehabilitation strategies might be adapted and optimized based on the findings of this study.
The questionnaires and measurements at the outpatient clinic will cost extra time for the patient. This includes patient history, RoM, CS and 3 self report questionnaires (SF-12, DASH and WORC). No physiological discomfort during test administration is to be expected.

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

Patients previously suffering a MRI proven massive RC tears of at least 5 cm (3), with involvement of the m. supraspinatus and m. infraspinatus (e.g. posterosuperior tears), for which they received a muscle transfer between 2003 and 2009.

Exclusion criteria

No informed consent, Insufficient Dutch Language skills

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2012
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO

Date:	08-02-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-07-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL38305.058.11