Dutch Arthoscopy Association Rotator Cuff Study

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The objective is to evaluate and compare the outcome of conventional open or arthroscopic rotator cuff surgery, by means of clinical scores and biomechanical studies (range of motion, scapulohumeral rhythm, muscle activation patterns).

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

Summary

ID

NL-OMON35617

Source
ToetsingOnline

Brief title
NRC-Study

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
cuff rupture; shoulder muscle rupture

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: t.b.v. addendum: Reumafonds en ZonMW-AGIKO,Nederlandse Vereniging voor Artroscopie

Intervention

Keyword: arthroscopic, cuff, repair, trial

Outcome measures

Primary outcome

Disabilities of Arm, Shoulder and Hand Score (DASH) at different follow up visits (pre-op; 6 wk; 3 mth; 6 mth; 12 mth; 24 mth).

Addendum:

Standardized RoM*s before and after surgery

Secondary outcome

Visual Analogue Scale for pain (VAS pain), Simple Shoulder Test (SST), Constant Murley score and clinical shoulder function 12 months post operatively. Evauation of cuff quality by MR-arthrography 12 months post operatively.

Addendum:

EMG shoulder muscle activation patterns during standardized tasks -->

Activation ratio

Study description

Background summary

Rotator cuff ruptures are one of the most prevalent medical conditions concerning the musculoskeletal system with considerable morbidity. Operative intervention in indicated when conservative treatment fails. This can be done by the conventional open repair surgery of by an arthroscopic procedure. The latter being a up and coming procedure with a lot of revolutionairy developments in the last decade. The major advantage is its minimally invasive

character. A study on open versus arthroscopic shoulder stabilisation surgeries showed an increase in cost effectiveness in favour of arthroscopy. A disadvantage is an extended learing curve. Furthermore there is speculation on the quality of the repair and the complication rate. At this point it is not clear wether there is a difference with regard to pain and function after conventional open or arthroscopic rotator cuff surgery.

Pathologic muscle activation patterns have been reported in patients with rotator cuff ruptures: activation of ADductors during ABduction in order to generate an increase in subacromial volume. It is unknown whether rotator cuff repair leads to normalization of this pathologic muscle activation patterns. Additionally, it is unknown whether rotator cuff repair is a useful procedure from a biomechanical viewpoint. Therefore, we will include the last 40 patients of the NRC-study for this addendum: a biomechanical study.

Study objective

The objective is to evaluate and compare the outcome of conventional open or arthroscopic rotator cuff surgery, by means of clinical scores and biomechanical studies (range of motion, scapulohumeral rhythm, muscle activation patterns).

Study design

A prospective randomised clinical trial in which the outcomes of conventional open or arthroscopic rotator cuff surgery performed by 1 orthopaedic surgeon are being compared. Flow chart on page 11 of the protocol.

Intervention

Conventional open and arthroscopic rotator cuff surgery.

Study burden and risks

No additional risk or increased complication rate, because both surgical procedures are standardised treatments in the orthopaedic practise.

Addendum:
2 visits at the LUMC for biomechanical studies (74 minutes). No additional risks.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Full thickness cuff rupture proven on MR-arthrography
* Signed Informed Consent form

Exclusion criteria

* age < 18 year; > 75 year
* neurologic etiology
* glenohumeral instability
* traumatic shoulder/old fracture
* frozen shoulder
* reumatoïd arthritis
* history of shoulder infection
* history of (attempt) cuff repair

* history of wound healing problems (dehiscence, infections e.g.)
* acromionresection
* cuff arthropathy
* perioperatively not able to close defect or partial thickness rupture
* non compliance with regard to follow up
* not capable of speaking and writting dutch language

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):	04-02-2008
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	28-11-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-01-2010

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-07-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL19378.098.07