Long term results of arthroscopic debridement of partial rotator cuff ruptures.

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The main objective of this study is to evaluate the long term results (minimum of 10 years) of arthroscopic debridement of the rotator cuff in the treatment of partial rotator cuff ruptures.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON41074

Source
ToetsingOnline

Brief title
LADPARC

Condition

- Bone and joint therapeutic procedures

Synonym
partial rotator cuff rupture

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arthroscopic, debridement, long term, partial, result, rotatorcuff

Outcome measures

Primary outcome

Long term results (minimum 10 years) of arthroscopic debridement of partial

rotator cuff ruptures as measured with the CMS.

Secondary outcome

n.a.

Study description

Background summary

A partial rotator cuff rupture is a common entity in shoulder pathology. The nature of this lesion can be degenerative, traumatic or a combination thereof. The patient complains of pain and dysfunction of the affected shoulder. A non-operative treatment (e.g. physical therapy) is the initial choice of treatment. In case this fails, surgical treatment can be considered. Short term results of operative treatment are reported to be good. It is however not known how patients fare on the long term. The purpose of this study is to evaluate the long-term results of arthroscopic debridement of partial rotator cuff ruptures performed in the Onze Lieve Vrouwe Gasthuis.

Study objective

The main objective of this study is to evaluate the long term results (minimum of 10 years) of arthroscopic debridement of the rotator cuff in the treatment of partial rotator cuff ruptures.

Study design

A physical examination (using CMS and flexion elbow test), a pain questionnaire, and an ultrasound test of the rotator cuff will be performed at the outpatient clinic. Patients will also be asked to fill out patient reported outcome measures (WORC, DASH, EQ5D and a patient satisfaction questionnaire) online at home.

Study burden and risks

n.a.

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

All patients diagnosed with a partial rotator cuff rupture, confirmed by MRI or ultrasound
All patients who received arthroscopic debridement at the department of orthopaedic surgery of the OLVG between January 2001 and December 2004;
Patients older than 18 years at the moment of diagnosis partial rotator cuff rupture;
Surgical intervention: debridement with or without acromioplasty

Exclusion criteria

Inadequate knowledge of Dutch language;
Post-operative incident of ipsilateral shoulder injury such as fractures or AC separation or shoulder dislocation;
Neurological conditions influencing upper limb;
Unable to visit the outpatient clinic to undergo CMS testing;

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	29-09-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL49627.100.14