Tenotomy of long head biceps tendon as a treatment for elderly patients with degenerative rotator cuff rupture.

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Study of functional outcome after arthroscopic tenotomy of long head biceps tendon vs. arthroscopic debridement vs. conservative treatment as treatment for degenerative rotator cuff ruptures in patients 65 years or older.

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

Summary

ID

NL-OMON43623

Source
ToetsingOnline

Brief title
LOBI-trial

Condition

- Tendon, ligament and cartilage disorders

Synonym
rotator cuff rupture, Shoulder tendon tear

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: geen subsidie

Intervention

Keyword: - (long head) biceps tendon, - rotator cuff rupture, - tenotomy, - treatment

Outcome measures

Primary outcome

Primary outcome measure is the Constant-Murley Score. With this as outcome measure we can compare the results to the current literature.

Secondary outcome

Secondary outcome is the Oxford Shoulder Score. Other questionnaires/tests where patients will be exposed to are the VAS pain score, EQ-5D questionnaire, Anchor questions questionnaire and the O'Brien test at the physical examination. We will also determine the size and anatomical location of the rotator cuff rupture on the MRI.

Study description

Background summary

A rupture of the rotator cuff is very common. In older patients, the risk of re-rupture after surgical repair is larger and the functional outcome less compared to surgical repair in younger patients. Symptomatic lesions of the long biceps tendon are common in patients with large rotator cuff ruptures due to clamping of the long biceps tendon between the acromion and the humeral head. Earlier research showed that after a spontaneous rupture of the long biceps tendon in general an improvement of the shoulder complaints occurred after a short period of acute pain. For those elderly patients where extensive rotator cuff repair is not a good option anymore, an arthroscopic tenotomy of long head biceps tendon could be an option. To date there is no evidence of how these patients to be treated the best.

Study objective

Study of functional outcome after arthroscopic tenotomy of long head biceps tendon vs. arthroscopic debridement vs. conservative treatment as treatment for

degenerative rotator cuff ruptures in patients 65 years or older.

Study design

Prospective randomized multicenter study where 126 patients will be enrolled in 7 centers with follow-up of 1 year. Randomization of the 3 treatment arms will be achieved equally by block randomization. Conservative treatment starts immediately after inclusion, surgical treatment within 6 weeks after inclusion. In addition to the baseline measurements, there will be times of measurements at 6 weeks, 3 months, 6 months and 12 months.

Intervention

Not applicable.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Since all three treatments are regular treatments for this patient category, there are no higher risks to expect compared to the usual care. At the measurement moments 15 minutes are extra calculated to fill out the questionnaires. The O'Brien test is performed once before initiating treatment at the physical examination, but this is a normal treatment. A MRI scan is normal care for this patient category and is no additional burden for the patient. With a minimal effort of the patient we can require a maximum of information to obtain de best possible care for this patient group. This is important, because there is no good treatment for this disease.

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

1) Age 65 years and older.
2) Clinical suspicion rotator cuff rupture with pain and/or weakness while testing supraspinatus tendon and/or infraspinatus tendon.
3) MRI of the affected shoulder, assessed by two evaluators as full thickness suprasprinatus and/or infraspinatus rupture with retraction at least grade 2 according to the scale of Patte and intact non-dislocated long head biceps tendon.
4) Signed informed consent.

Exclusion criteria

1) Frozen shoulder (in more than 3 directions less than 50% of the normal range of motion, passive examination)
2) Symptomatic AC-artrosis on the ipsilateral side.
3) (Reumatoïd) arthritis
4) Diabetes Mellitus (type 1 and 2).
5) Language barrier or cognitive problem (not able to fill in the questionnaires).
5) Neurologic problems with functional shoulder complaints.
6) Surgical treatment in the past in the same shoulder.
7) Glenohumoral osteoarthritis
8) Inclusion of the contralateral shoulder in this study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL54517.075.15
Other	NTR-nummer volgt.