Bicepspees tenodese of tenotomie bij arthroscopische rotator cuff repair: Een internationaal multicenter prospectief gerandomiseerde klinische trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20398

Source
NTR

Brief title
BITE

Health condition

Rotator cuff, Arthroscopic treatment, Bicepstendon, Popeye, Cosmesis

Sponsors and support

Primary sponsor: OLVG Amsterdam
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Functional outcome measured using the Constant score.

Secondary outcome

In addition, the Dutch Oxford Shoulder Test (DOST) and the Disabilities of the Arm Shoulder and Hand (DASH) questionnaire will be assessed. Other evaluations concern: cosmetic appearance evaluated by the ‘‘Popeye’’ deformity, arm cramping pain, elbow flexion strength (measured with a hand dynamometer), cost-effectiveness (evaluated with the EQ-5D), and an MRI evaluation.

Study description

Background summary

During arthroscopic rotator cuff (infraspinatus/supraspinatus) repair, biceps tendon lesions are frequently encountered. However, the most optimal treatment of the diseased long head of the biceps (LHB) tendon during rotator cuff repair remains a topic of debate: tenotomy or tenodesis. Our hypothesis is that there is no difference in functional outcome between LHB tenotomy and LHB tenodesis when performed in adjunct to arthroscopic rotator cuff repair. An International, Multicenter, Prospective Randomized Controlled Trial.

Study objective

LHB tenotomy does not lead to inferior functional results as compared to LHB tenodesis when performed in conjunction with an arthroscopic repair of a moderately sized rotator cuff (supraspinatus/infraspinatus tendon) tear in patients 50 years or older.

Popeye deformity after LHB tenotomy or LHB tenodesis is not clinically relevant. LHB tenotomy is associated with a favorable cost-utility.

Study design

At the initial visit (pre-op), the treating physical will determine the Constant score and the elbow flexion power. An MRI and digital photograph are taken from the upper arm to assess cosmetic changes postoperatively by a blinded independent assessor). In addition, all subjects will complete a questionnaire with demographic information, questions on general pain and pain in the bicipital groove, the Dutch translation of the Oxford shoulder test, the DASH and EQ-5D. In case of definite inclusion (e.g. in case a significant biceps pathology was found during arthroscopic surgery and the patient was randomized to Group 1 or Group 2), this will be repeated (in part or in full) at three post-operative assessments (e.g. 6 weeks, 3 months, one year), in addition to assessment of cosmetic changes.

Only at the final follow up (1 year) the MRI will be repeated.

Intervention

Long head biceps tenodesis or tenotomy in arthroscopic rotator cuff repair.

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Eligibility criteria

Inclusion criteria

Patients older than 50 years who are indicated to undergo repair of a moderately sized rotator cuff (infraspinatus and/or supraspinatus) tendon rupture (sized smaller than 3cm measured using an arthroscopic ruler), who are encountered with an inflamed, unstable or partially torn LHB tendon.
Patients need to be able to read and write in Dutch or English language in order to complete the questionnaires, and sign informed consent.

Exclusion criteria

Patients are excluded form this study in case of an acute, traumatic or partial thickness rotator cuff rupture, or in case a full thickness tear is larger than 3 cm measured using an arthroscopic ruler. (This excludes patients who have a massive rotator cuff rupture, since these patients are more likely to have a re-rupture within one year).

Patients are also excluded when the origo of the bicepstendon has an hour-glass aspect or in

case of accompanying subscapularis tendon rupture.
Pre-operative X-ray of the involved shoulder revealing acromion to humeral head distance measuring 6mm or smaller or osteoarthritis also excludes patients from participation to this study.
Any prior surgery to the involved shoulder leads to exclusion from participation in this study.
Dementia or inability to complete questionnaires and assessments excludes patients form this study as well.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	98
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-01-2012
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	NL3107
NTR-old	NTR3255
Other	VCMO : WO 10.087
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A