Long head biceps tenodesis or tenotomy in arthroscopic rotator cuff repair: An international multicenter prospective randomized clinical trial.

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To compare the functional results of LHB tenotomy and LHB tenodesis when performed in adjunct to arthroscopic rotator cuff repair.

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

Summary

ID

NL-OMON44133

Source
ToetsingOnline

Brief title
BITE

Condition

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

Synonym
Long head bicepstendon pathology, rotatorcuff surgery

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: Bicepstendon, Cosmesis, Rotator cuff, Strength

Outcome measures

Primary outcome

Patient evaluation is conducted with a focus on overall shoulder function, as evaluated with the Constant score. In addition, the Dutch Oxford Shoulder Test and the Disabilities of the Arm Shoulder and Hand questionnaire will be assessed.

Secondary outcome

Other evaluations concern: cosmetic appearance evaluated by the **Popeye** deformity, arm cramping pain, elbow flexion strength (measured with a hand dynamometer), and quality of life and cost-utility (evaluated with the EQ-5D).

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.

Study objective

To compare the functional results of LHB tenotomy and LHB tenodesis when performed in adjunct to arthroscopic rotator cuff repair.

Study design

An International, Multicenter, Prospective Randomized Controlled Trial

Intervention

In addition to arthroscopic rotator cuff repair one group is treated by performing LHB tenotomy and the other group is treated by performing an LHB tenodesis.

Study burden and risks

We do not anticipate treatment related risks related to participation in this study, but it is possible (though unlikely) that one treatment method will prove inferior to the other with respect to postoperative functional outcome or satisfaction. Treatment of LHB tendon lesions is performed differently around the world. Studies addressing the differences in outcome between the two treatment variations showed comparable results. If this study confirms our hypothesis, our patients will not have to undergo LHB tenodesis. This potentially avoids complications associated with an added procedure of the LHB tenodesis to an arthroscopic rotator cuff repair. This is probably less costly in terms of time and material as well.

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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 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.
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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2013
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2014

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-11-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-04-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-11-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-11-2017
Application type:	Amendment
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	NL37898.100.11