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Surgery for long head of biceps brachii tendon lesions

Submission date
06/05/2012

Recruitment status
Stopped

Registration date
31/05/2012

Overall study status
Stopped

Last Edited
23/06/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The biceps, also known as the biceps brachii, is a two-headed muscle that lies on the upper arm between the shoulder and the elbow. It is attached to the bones of the shoulder and elbow by strong cords of fibrous tissue called tendons. Lesions (damage) of the long head of the biceps brachii tendon (LHBT) are common and when not adequately treated, they may be responsible for persistent pain as well as functional impairment of the shoulder. LHBT lesions can be isolated but are more frequently associated with more complex diseases, such as shoulder instability or supraspinatus tendon tears. The two most common surgical procedures for LHBT lesions are biceps tenotomy and biceps tenodesis. In biceps tenotomy the long head of the biceps tendon is released from its attachment in the shoulder joint, allowing it to fall down. In biceps tenodesis the biceps tendon is released from the shoulder joint and reattached to the arm bone. Currently, there is no consensus regarding the most effective surgical procedure due to the inconsistent results and the limitations of published studies. Some claim that tenotomy is superior, reporting satisfactory results in most of the patients treated with this technique. The advantages of tenotomy include its greater ease of execution, and when it is performed alone, it requires fewer restrictions after surgery with an earlier return to activity. Others report similarly good results in most patients treated with tenodesis of the LHB avoiding some of the most common complications associated with tenotomy, such as cramping of the brachial biceps muscle, retraction of the biceps tendon and strength decrease of the arm and forearm. The aim of this study is to compare the effectiveness of tenotomy and tenodesis in the treatment of LHBT lesions.

Who can participate?
Patients aged 18 or over with LHBT lesions associated with supraspinatus tendon tears

What does the study involve?
Participants are randomly allocated to undergo either long head biceps tenotomy or tenodesis and the outcomes of the two groups are compared.

What are the possible benefits and risks of participating?
The surgical treatments are routinely used in the centers involved in the study.

Where is the study run from?
1. Villa Verde Clinic (Italy)
2. Magna Græcia University (Italy)

When is the study starting and how long is it expected to run for?
January 2012 to January 2015

Who is funding the study?
Magna Græcia University (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Tenotomy versus tenodesis in the treatment of the long head of biceps brachii tendon lesions: a randomized controlled study

Study objectives
Most of the studies comparing the results of long head biceps (LHB) tenodesis and tenotomy are limited by methodologic deficiencies such as a retrospective design, low statistical power or a lack of patient randomization. To the best of our knowledge, there are no double-blind

randomized controlled trials on this topic. The purpose of this study is to compare the effectiveness of tenodesis and tenotomy in the treatment of LHBT lesions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Azienda Ospedaliera Mater Domini, Catanzaro, Italy, ref: 2011-57

Study design
Two-center randomised double-blind controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lesions of the long head of the biceps brachii tendon (LHBT)

Interventions
The two most common procedures for LHBT lesions are biceps tenotomy and biceps tenodesis. Both procedures will be performed in the lateral decubitus position. A routine glenohumeral diagnostic arthroscopy will be performed through a standard posterior arthroscopic portal; lateral and rotator interval anterior portals will be used to complete the surgery. Reconstruction of the supraspinatus tendon tear will be always performed.

The surgeon will be aware of the type of surgery being performed, but the physicians who will take care of the follow-up visits and who will collect the pre- and post-operative data of patients will be blinded to the surgical technique used to treat the patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Constant-Murley scores (CMS) at the two-year follow-up

Key secondary outcome(s))
1. General health evaluated by Short Form 36 (SF-36) score
2. The number and severity of complications

Completion date
01/01/2015

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Male or female patients
2. Aged 18 or older
3. LHBT lesions (tenosynovitis, subluxation, dislocation or partial rupture of the tendon) associated with supraspinatus tendon tears

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous surgery of the affected shoulder
2. Insufficient comprehension of the Italian language to understand the trial features
3. Mental handicap
4. A lack of willingness to return for all scheduled follow-up visits
5. Participation in another study
6. Any previous upper extremity neurological disorder or diagnosis based upon physical examination
7. A life expectancy of less than 2 years
8. An ongoing insurance trial, lawsuit, or pending legal action for shoulder disease

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Italy

Study participating centre
University Magna Graecia
Dept. of Medical and Surgical Sciences
Catanzaro
Italy
88100

Sponsor information

Organisation
Hospital Mater Domini (Azienda Ospedaliera Mater Domini) (Italy)

ROR
https://ror.org/03q658t19

Funder(s)

Funder type
University/education

Funder Name
Magna Graecia University of Catanzaro (Italy) - Department of Surgical and Medical Science

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes