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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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## 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 measure
Constant-Murley scores (CMS) at the two-year follow-up

### Secondary outcome measures
1. General health evaluated by Short Form 36 (SF-36) score
2. The number and severity of complications

### Overall study start date
01/01/2012

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
128

### 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)

### Sponsor details
Via T. Campanella, 115
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+39 (0)961 712111
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### Sponsor type
Hospital/treatment centre

### Website
http://www.aomaterdomini.it/comitatoEtico.php

### 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |