# Cutting the long biceps tendon as a treatment for elderly patients with a shoulder tendon rupture.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | - |

## Summary

### ID

NL-OMON22910

**Source**
NTR

**Brief title**
BITE-study

**Health condition**

- Lange bicepspees tenotomie
- Rotator cuff ruptuur
- Impingement lange bicepspees

- Tenotomy of the long head of the biceps tendon
- Rotator cuff rupture
- Impingement long biceps tendon

### Sponsors and support

**Primary sponsor:** C.T. Koorevaar (principal investigator, orthopedic surgeon Deventer Hospital)
A.V. Boeddha (coordinating investigator, orthopedic surgeon in training Deventer Hospital)
**Source(s) of monetary or material Support:** fund = initiator = sponsor = Koorevaar+Boeddha

## Intervention

## Outcome measures

### Primary outcome

Constant-Murley Score (CMS)

### Secondary outcome

Oxford Shoulder Score (OSS)

# Study description

### Study design

T0=baseline

T1=6 weeks

T2=3 months

T3=6 months

T4=12 months

### Intervention

Multicenter randomised controlled study in which patients are recruited for one year. There will be three treatment groups in which patients can be randomised: arthroscopic tenotomy long head biceps tendon vs. arthroscopic debridement vs. conservative treatment (physical therapy). The study will be conducted at the orthopedic department of the Deventer Hospital, Martini Hospital Groningen, Leeuwarden Medical Centre and Orthopaedic Center East Netherlands (Hengelo / Almelo).

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 65 years or more

2. Clinical suspection rotator cuff rupture with pain and/or weakness of the supraspinatus tendon or infraspinatus tendon

3. MRI of the affected shoulder, by two reviewers assessed as full thickness supra- and/or infraspinatus tendon rupture with intact and non-dislocated long head of the biceps tendon.

4. Signed informed consent.

## Exclusion criteria

1. Frozen shoulder (in more than three directions less than 50% of the normal range of motion when passive physical examination is done).

2. Symptomatic AC-arthrosis ipsilateral side.

3. (Reumatoid) arthritis.

4. Diabetes Mellitus (type 1 and 2).

5. Language barrier/ cognitive problems (not capable to fill in questionnaires).

6. Neurologic problems with functional shoulder complaints.

7. Surgery in the past in the concerning shoulder.

8. Glenohumoral osteoarthritis.

9. Inclusion of the other shoulder in this study.

# Study design

## Design

| | |
|---|---|
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |

**Control:** N/A , unknown

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2015 |
| Enrollment: | 120 |
| Type: | Anticipated |

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# 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 | NL5594 |
| NTR-old | NTR5700 |
| Other | METC Zwolle : 15.08131 |

# Study results