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

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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...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20398

**Bron**
NTR

**Verkorte titel**
BITE

**Aandoening**

Rotator cuff, Arthroscopic treatment, Bicepstendon, Popeye, Cosmesis

### Ondersteuning

**Primaire sponsor:** OLVG Amsterdam
**Overige ondersteuning:** Not applicable

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Functional outcome measured using the Constant score.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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.

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-06-2012 |
| Aantal proefpersonen: | 98 |
| Type: | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 18-01-2012 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3107 |
| NTR-old | NTR3255 |
| Ander register | VCMO : WO 10.087 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A