Cost-effectiveness of biceps tenotomy with or without cuff repair in patients with stage 2-3 Goutallier fatty degenerative cuff lesions. A randomized controlled trial

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

Samenvatting

ID

NL-OMON26658

Bron
Nationaal Trial Register

Verkorte titel
TenCure

Aandoening

Arthroscopic cuff repair
Cuff tear / cuff ruptuur
Bicepstenotomy / Bicepstenotomie
Stage 2-3 Goutallier / stadium 2-3 Goutallier

Ondersteuning

Primaire sponsor: Performer: St. Antonius Ziekenhuis, Utrecht/Nieuwegein
Overige ondersteuning: The foundation of medical research of the St. Antonius Hospital grant number [14.8]

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome will be quality of life (QOL) measured by the Western Ontario Rotator Cuff (WORC) Index 6 months after surgery. The WORC index is a disease-specific shoulder questionnaire, originally developed at the University of Western Ontario and has been validated in Dutch [24]. It measures quality of life in patients with rotator cuff disease on 5 domains: physical symptoms, sports and recreation, work, lifestyle and emotions. Each item is scored on a non-hatched 100-mm visual analogue scale (VAS). Total score ranges from 0 to 2100, with a higher score indicating a lower quality of life. All items are converted to a score from 0-100%, with a higher score indicating a higher QOL.
In addition, an economic analysis will be performed from a societal perspective and a budget impact analysis from societal, government and insurer perspective.

Toelichting onderzoek

Achtergrond van het onderzoek

this multicentre randomized controlled trial is designed to compare the short and long term outcome of patients who underwent an arthroscopic tenotomy of the long head of the biceps tendon with or without a cuff repair. The primary parameter is the rotator cuff specific quality of life (Western Ontario Rotator Cuff index)) on the short term (6 months after surgery). Secondary parameters are quality of life on the long term and function (glenohumeral range of motion, Constant Murley score), recovery status, pain (Visual Analogue Scale), productivity losses (TiC-P), satisfaction of treatment on the short and long term and re-tear rate at 6 months determined with an ultrasound. We hypothesize that patients who undergo an isolated tenotomy of the long head of the biceps tendon in the presence of a degenerative rotator cuff tear, stage 2-3 Goutallier fatty infiltration, will have better functional results and quality of life, 3 and 6 months after surgery as compared to patients undergoing tenotomy combined with rotator cuff repair, due to the less extensive procedure and the less restrictive rehabilitation protocol. At 1 year after surgery and on the long term (up to 5 years after surgery), we assume equal improvement of function results and quality of life in both groups and reduced costs with isolated tenotomy treatment.

Doel van het onderzoek

• We expect more functional improvement and a higher level of quality of life 3 and 6 months postoperatively for patients undergoing an isolated bicesptenotomy (measured with: WORC, RAND-36, EQ-5D-5L, VAS pain, CMS, glenohumeral range of motion).

• We expect after one year and up to five years that functional improvement and quality of life will be equal for both groups (measured with: WORC, RAND-36, EQ-5D-5L, VAS pain, CMS, glenohumeral range of motion).

• We expect that patients undergoing an isolated bicesptenotomy will resume work / daily activities much faster because after surgery their shoulders are directly functional without any restrictions. The patients who undergo a rotator cuff repair will be immobilized for 6 weeks in an abduction or anti-rotation sling and will need an additional 6 weeks for functional recover, which will lead to more productivity losses.

• We expect that surgery for patients undergoing an isolated bicesptenotomy will be shorter and less surgical instruments/materials will be used.

• We expect with an equally improvement of function in both groups, that an isolated bicepstenotomy in the setting of a grade 2-3 Goutallier FI rotator cuff tear is much more cost-effective than performing an additional cuff repair as standard therapy.

• We expect adverse events to occur more frequently in the cuff repair group.

Onderzoeksopzet

Preoperatively (baseline)
Postoperatively: 6 weeks, 12 weeks, 6 months, 1 year, 2 years, 3 years, 4 years. 5 years.

Onderzoeksproduct en/of interventie

The procedures are only performed by an orthopaedic surgeon experienced in arthroscopic rotator cuff surgery. Surgical technique, such as patient positioning, portal placement and the use of assistive instruments such as knives, forceps, shavers and RF-probe will be done or used according to the standard protocol at the site. The used of preoperative antibiotics, technique used for repair (if possible double row rotator cuff repair) and post-operative rehabilitation protocols will be standardized. During the arthroscopic procedure the following anatomical structures will be evaluated: capsula, synovium, bursae, labrum, long head of biceps tendon (aspect, mobility), rotator cuff tendons/ muscles (aspect, mobility), articular surface, subacromial space and ligaments.

Group 1: bicepstenotomy with cuff repair:
After surgery they will be immobilized for 6 weeks in an abduction or anti-rotation sling. Two weeks after surgery the patients will visit the outpatient department for wound inspection and removal of stitches. After six and twelve weeks they will be checked on function and persistence of symptoms. Patients will be referred to a physiotherapist immediately after discharge of the hospital to assist in the passive mobilization of the shoulder during the first 6 weeks, and the active mobilization after 6 weeks.

Group 2: bicepstenotomy without cuff repair:
After surgery shoulders are directly function without any restrictions. A simple sling can be given to support the arm during the recovery period from surgery.

Contactpersonen

Publiek

Afdeling Orthopedie
St. Antonius Ziekenhuis
Postbus 2500
Nienke Wolterbeek
Nieuwegein 3430 EM
The Netherlands
+31 88 3202325

Wetenschappelijk

Afdeling Orthopedie
St. Antonius Ziekenhuis
Postbus 2500
Nienke Wolterbeek
Nieuwegein 3430 EM
The Netherlands
+31 88 3202325

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Competent men and women older than 18 years

- Willing and able to comply with the study protocol

- Signed informed consent

- Cuff lesion with at least one of the involved tendons having stage 2-3 Goutallier fatty infiltration

- Involvement of the long head of the biceps tendon (one or more of these clinical tests found

positive: painful bicepsgroove, Speed test, Yergason’s test, O’Brien’s test, Habermeyer’s test or obvious tendinopathy on MRI) or preoperative pathologic aspect of its intra-articular part

- Failed conservative treatment (> 6 months) of their subacromial pain syndrome

- Sufficient understanding of the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Cuff arthropathy according Hamada classification > grade 2

- Full subscapularis tendon tear (delamination or partial avulsion accepted)

- Injury of the teres minor tendon

- Mainly complaints from acromioclavicular origine compared to subacromial pains, determined clinically or by subacromial/acromioclavicular infiltration (acromioclavicular joint resection is not an exclusion criteria)

- Shoulder instability for which labral repair is indicated

- Irreparable rotator cuff tear based on preoperative MRI, or on peroperative findings.

- Unsuccessful surgery in the affected shoulder in history or surgery in the affected shoulder < 1 year ago

- Ipsilateral neurological pathology possibly affecting functional outcome

- Full tear of the biceps tendon

- Unimpaired biceps tendon during arthroscopy

- Cervical spine pathology affecting the functional outcome

- Body Mass Index (BMI) > 35 kg/m^2

- Time between surgery and MRI > 12 months

- Fracture of the humeral head involved in the cuff tear

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	22-10-2018
Aantal proefpersonen:	172
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47699
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4010
NTR-old	NTR4182
CCMO	NL54313.100.15
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47699

Resultaten

Samenvatting resultaten
N/A