Superior capsular reconstruction of irreparable degenerative rotator cuff tears of the shoulder: a multi-center,comparative, prospective, observational follow-up study

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To investigate the effect of superior capsular reconstruction in patients with an irreparable degenerative rotator cuff tear on pain and function. Secondary, complications will be monitored and radiographic analyses performed as safety measures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON48664

Source
ToetsingOnline

Brief title
Superior capsular reconstruction of rotator cuff tears

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
degenerative rotator cuff tear, wear and tear shoulder tendon

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Fonds Wetenschap en Innovatie VieCuri

Intervention

Keyword: degenerative tear, reconstruction, rotator cuff, surgery

Outcome measures

Primary outcome

The main study parameter is the functional outcome, measured using the Constant-Murley score (including a patient questionnaire and measurements of Range of Motion and muscular strength).

This will be measured pre-operatively and at 3, 6, 12 and 24 months post-operatively as well as 5 and 10 years post-operatively.

Secondary outcome

Furthermore, pain (NRS-score), function (Disabilities of Arm Shoulder and Hand (DASH) questionnaire) and quality of life (SF12) will be measured and X-rays will be taken to evaluate possible (re)tears.

All parameters will be measured pre-operatively and at 3, 6, 12 and 24 months post-operatively, as well as 5 and 10 years post-operatively. Only the radiographs at 3 months will not discarded, since an X-ray is already taken directly post-opeartive, conform standard care.

Study description

Background summary

Degenerative rotator cuff tears are common in the elderly and can cause serious

pain and functional limitation. When conservative treatment fails, (arthroscopic) rotator cuff repair can be considered. In case of a massive rotator cuff tear, primary rotator cuff repair is not possible and a reversed shoulder prosthesis can be considered. This is an invasive surgery, with an increased risk of serious complications and no guarantee of complete recovery of function.
Superior capsular reconstruction is a new technique that enables to recover the superior capsule by suturing an *acellular dermal matrix* to the glenoid and the humeral head to overcome the rotator cuff tear. This technique is joint-saving and therefore less invasive and presumably has a lower chance of complications than a reversed shoulder prosthesis. This technique is now standard-of-care in VieCuri Medical Centre and clinc ViaSana. Superior capsular reconstruction can be performed with different types of*acellular dermal matrix, namely porcine graft or human graft. For both types of allografts the first results of superior capsular reconstruction are promising, but until now, long term results are unknown.
We hypothesize superior capsular reconstruction results in a decline of pain and restoration of function without severe complications, and no significant differences in primary and secondary outcomes will be found between the two types of allografts.

Study objective

To investigate the effect of superior capsular reconstruction in patients with an irreparable degenerative rotator cuff tear on pain and function. Secondary, complications will be monitored and radiographic analyses performed as safety measures.

Study design

Non-comparative prospective observational follow-up study

Intervention

Arthroscopic superior capsular reconstruction. Through an arthroscopic surgical procedure, an acellular dermal matrix is sutured to the glenoid and the head of the humerus to overcome the rotator cuff tear.

Study burden and risks

The measurement of pain and function outcomes necessary for this study is standard care for all patients that undergo surgery for shoulder pathology, except for the muscle strength and questionnaires, and for 3 additional visits (at 2, 5 and 10 years post-operatively). Furthermore, patients receive four additional X-rays (at 1,2,5 and 10 years post-operatively). Additional measurements and X-rays will be combined with regular care visits as much as

possible to limit the impact of the study related activities on participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age > 40 years;
Patiënts with a clinical suspicion of a rotator cuff tear scheduled for arthroscopic superior capsular reconstruction;
Patients have signed informed consent.

Exclusion criteria

Patients with rheumatoid arthritis
The inability to understand Dutch language
Patients with neurologic impairment influencing functioning affected limb

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2018
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	DX Reinforcement Matrix and ArthroFLEX
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-05-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	29-10-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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
CCMO	NL63564.068.17

Study results

Date completed: 05-05-2021

Actual enrolment: 17

Summary results
Trial ended prematurely