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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26842

Source
Nationaal Trial Register

Brief title
SCR

Health condition

Degenerative rotator cuff tear of the shoulder

Sponsors and support

Primary sponsor: VieCuri Fonds wetenschap en innovatie
Source(s) of monetary or material Support: Initiator=sponsor

Intervention

Outcome measures

Primary outcome

The primary outcome measurement is functioning, measured with the Constant-Murley score (CMS)

Secondary outcome

Secondary outcomes are: Functional limitations of arm, shoulder, hand in daily activities (measured by DASH); quality of life (measured with SF-12); pain (measured with NRS scale); Patient satisfaction (measured with NRS scale and 3 anchor questions using a Likert scale about improvement in pain relief, functioning, and recovery of symptoms); Acromiohumeral distance in mm(determined by means of X-ray); tears of the graft (determined based on MRI); presence of frosen shoulder (determined by clinical examination); occurance of (serious) adverse events

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. A few years ago, a new arthroscopic technique was introduced, capable of repairing massive rotator cuff tears. This so-called superior capsular reconstruction (SCR) restores 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. Superior capsular reconstruction could be performed with different types of allografts as ‘acellular dermal matrix’: porcine graft or human graft. For both types of allografts Tthe first results of superior capsular reconstruction are promising, although follow-up was relatively short so far. This study is set up to investigate long term effects of superior capsular reconstruction with porcine graft compared to human allograft. We hypothesize superior capsular reconstruction results in a decline of pain and restoration of function without severe complications and with no differences between the porcine and human allograft.This study aims to investigate the results of superior capsular reconstruction in terms of pain and function, and to evaluate the outcomes of porcine graft compared to human allograft in patients with an irreparable degenerative rotator cuff tear. Secondary, radiographic and MRI analyses will be performed to monitor complications. The objectives of this study are to investigate the effect of superior capsular reconstruction with porcine graft compared to human allograft in patients with an irreparable degenerative rotator cuff tear on pain and

function. Secondary, complications will be monitored and radiographic and MRI analyses performed as safety measures.This study is a multicenter, comparative, prospective, longitudinal observational study. One center (VieCuri Medical Center, Venlo, The Netherlands) will perform superior capsular reconstruction with the porcine graft. The other participating center (ViaSana, Mill, The Netherlands) will perform superior capsular reconstruction with the human allograft.

Study objective

Our hypothesis is that patients show an increase in the CMS that is at least as good as reported results from reversed shoulder arthroplasty. We hypothesize that the effect of this procedure will last on the long term. Furthermore, we hypothesize no differences in this effect will be found between porcine and human allograft.

Study design

Pre-operative; postoperative outpatient follow-up visits will occur at 3, and 6 months and 1, 2, 5 and 10 years

Intervention

Arthroscopic superior capsular reconstruction by means of a porcine graft or human allograft.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for participation in this study are:

- Age ≥ 40 years
- Patiënts with a symptomatic, irreparable degenerative rotator cuff tear, who are scheduled for arthroscopic superior capsular reconstruction rotator cuff tear scheduled for arthroscopic superior capsular reconstruction
- Patients who provided written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- reumatoid arthritis
- inability to understand Dutch
- neurologic impairment influencing functioning affected limb

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2018
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-04-2019
Application type:	First submission

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	NL7681
Other	METC : METC173042

Study results