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

Gepubliceerd: 18-04-2019 Laatst bijgewerkt: 18-08-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26842

Bron
Nationaal Trial Register

Verkorte titel
SCR

Aandoening

Degenerative rotator cuff tear of the shoulder

Ondersteuning

Primaire sponsor: VieCuri Fonds wetenschap en innovatie
Overige ondersteuning: Initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

VieCuri Venlo
Vivian Bruls

0032773205129

Wetenschappelijk

VieCuri Venlo
Vivian Bruls

0032773205129

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-05-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-04-2019
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	NL7681
Ander register	METC : METC173042

Resultaten