

Superior Capsular Reconstruction: A registry study

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Patients undergoing superior capsule reconstructions (SCR) for superior shoulder instability will experience less pain (decrease of at least 2 points) and improved function.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21377

Bron

NTR

Verkorte titel

SCR

Aandoening

superior capsular reconstructions; shoulder; instability; rotator cuff; kapselreconstructie; cuff scheur; schouder instabiliteit

Ondersteuning

Primaire sponsor: St. Antonius Ziekenhuis

Overige ondersteuning: Initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome will be change in pain score (Numeric Rating Scale: 0-10) at 1 year after surgery. A decrease of 2 points in pain is considered to be a clinical relevant decrease.

A decrease in pain is expected from 12 weeks on, although patients will not be fully functional and are still in their rehabilitation process until one year after surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this study is to determine if patients with irreparable supraspinatus tears who receive a dermal Extracellular Matrix to reconstruct the superior capsule during arthroscopic rotator cuff repairs have improved functional and clinical outcomes. This concerns a observational register study focused on superior capsular reconstruction

Doel van het onderzoek

Patients undergoing superior capsule reconstructions (SCR) for superior shoulder instability will experience less pain (decrease of at least 2 points) and improved function.

Onderzoeksopzet

pre-operative; 3 weeks, 12 weeks, 6 months, 1 year, 2 years, 5 years post-operatively

Onderzoeksproduct en/of interventie

All subjects will undergo a superior capsular reconstruction (SCR).

Contactpersonen

Publiek

Afdeling Orthopedie

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The Netherlands

Wetenschappelijk

Afdeling Orthopedie

St. Antonius Ziekenhuis

Postbus 2500

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Subjects that have consented to implantation of allograft tissue
- Adult patients (≥ 18 year)
- Subjects who are candidates and planning to undergo arthroscopic SCR for irreparable supraspinatus tears
- Pre-operative MRI obtained within 26 weeks prior to surgery
- Must have 3 out of 5 points on MRC scale for external rotation strength (Appendix I)
- Must have intact teres minor

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pre-Op exclusion criteria

- Pregnant or planning to become pregnant
- Persons with a mental or cognitive disability deemed significant enough that they would not be capable of completing the outcome measures
- Patients with known contraindications to MRI
- Greater than 20 degrees loss of passive range of motion (ROM) compared to the contralateral side
- Grade 4 or 5 Hamada classification
- Pectoralis major, Deltoid, or Latissimus dorsi dysfunction
- Acute fractures of humerus, clavicle or scapula

- Intra-articular injections (steroids) within 1 month of surgery
- Inability to speak and understand Dutch

Intra-Op Exclusion

- Damaged coracoacromial ligament
- Unable to fixate the graft on the humeral side utilizing a double row SpeedBridge repair
- Inability to address subscapularis pathology
- Diffuse bipolar cartilage loss

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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	NL6756
NTR-old	NTR7625
CCMO	NL65778.100.18

Resultaten

Samenvatting resultaten

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