Superior Capsular Reconstruction: A registry study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21377

Source
NTR

Brief title
SCR

Health condition

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

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: Initiator = sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Outcome measures will be assessed through validated outcomes scoring systems. Secondary outcomes include function measured by the Constant Murley Score (CMS), the American Shoulder and Elbow Score Objective Score (ASES objective), RAND 12-Item Health Survey (RAND-12), Single Assessment Numeric Evaluation score (SANE), American Shoulder and Elbow Score subjective score, (ASES subjective) and the Western Ontario Rotator Cuff (WORC) index. In addition, MRI will be utilized to assess the status of the remaining rotator cuff tendons and SCR (healing versus non-healing). Ultrasound will be utilized to assess the thickness of the graft as compared to pre-op thickness and vascularization of the graft. Standard radiographs will be utilized assess the acromiohumeral interval and level of arthritic change as measured by the Hamada scale. Adverse event information will be documented as occurs. The following table outlines the outcome measures and time points for data collection. All follow-up moments are regular care, however, at every follow-up moment, extra data will be collected.

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	15

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL6756
NTR-old	NTR7625
CCMO	NL65778.100.18

Study results

Summary results
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