Randomized trial Evaluating first time shoulder Dislocation: sUrgery vs Conservative carE (REDUCE)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON57132

Source
ToetsingOnline

Brief title
REDUCE

Condition

- Joint disorders

Synonym
Shoulder dislocation

Research involving
Human

Sponsors and support

Primary sponsor: McMaster University
Source(s) of monetary or material Support: McMaster University

Intervention

Keyword: Instability, Shoulder dislocation

Outcome measures

Primary outcome

The success of the pilot study will be based upon the following a priori thresholds:

1. 50 patients recruited within 10 months;

2. 42 of 50 participants (85%) achieving complete follow-up at two years;

3. 85% of patients allocated to surgical intervention receiving surgery within 3 months of enrollment;

4. Less than 5 crossovers* between both groups.

*Note: Crossovers are defined as either: 1) participants randomized to non-operative management (control group) who choose to undergo surgery in the absence of any feelings of recurrent instability or re-dislocation; or 2) participants randomized to surgical intervention who opt out of surgery prior to surgical intervention and choose to undergo primary non-operative management.

We will confirm feasibility with a *traffic light* approach to determine if the definitive trial will be feasible, require modifications or will not be feasible.

Secondary outcome

The secondary objectives of the pilot trial will be the clinical objectives of the definitive trial:

1. Rates of recurrent shoulder dislocations up to 24 months* post-treatment;

2. Symptoms of instability without dislocation up to 24 months post treatment;

3. Clinical outcomes measured by Western Ontario Shoulder Instability (WOSI) Index, American Shoulder and Elbow Society (ASES) score, Shoulder Activity Scale, EQ-5D, Visual Analog Scale (VAS) Pain Score, and Patient Satisfaction questionnaire;

4. Physical examination: range of motion, strength, stability;

5. Return to previous level of activity and work, and;

6. Safety, shoulder-related complications and serious adverse events.

Hypothesis: We believe that the pilot trial will be feasible in our ability to recruit participants rapidly and meet our feasibility objectives.

Study description

Background summary

The shoulder is the most commonly dislocated joint in the body with a global incidence that ranges from 15 to 25 per 100 000 people. The estimated annual societal cost in North America due to first-time shoulder dislocations exceeds $1.2 billion CAD.
Anterior dislocations, the most common type of shoulder dislocation, are often complicated by subsequent instability and recurrent dislocation, with reported rates as high as 47%. Shoulder instability commonly results in pain and negatively impacts quality of life.
Current standard of care suggests surgical stabilization of the shoulder after two or more dislocations, but the evidence is far from conclusive.
Observational studies suggest that early surgical stabilization has strong biological rationale in limited risks of recurrent dislocation, improving quality of life, and potentially decreasing the future risk of shoulder arthritis. Also, some economic health studies suggests that surgery is less costly and more effective, even after recurrent dislocations.

Study objective

The primary objective of the pilot study is to assess the feasibility of a definitive trial to determine the effect of arthroscopic soft tissue

stabilization vs. non-surgical treatment on rates of recurrent anterior dislocation and functional outcomes in patients presenting with a first-time dislocation (FTD) over a 24-month period.

Study design

We propose a multi-centre pilot RCT of 50 participants across Canada, the United States, South America, and Europe to compare the effect of arthroscopic soft tissue stabilization (Bankart procedure) and non-operative treatment (physical therapy) in patients with a post-traumatic anterior FTD. Eligible and consenting participants will be followed-up by the site for 24 months. Outcomes will be assessed at 6 weeks, 6 months, 12 months, and 24 months post-treatment.

Intervention

Participants will undergo arthroscopic soft tissue stabilization (Bankart procedure) or non-surgical treatment as described below.

Arthroscopic Stabilization (Intervention)
Patients randomized to surgical intervention will be required to undergo surgery within 3 months of enrollment. Advanced imaging will be obtained prior to surgery, including MRI, MR arthrogram or preoperative CT scan for assessment of pathology. For arthroscopic Bankart repair, the participant will be placed in the lateral decubitus or beach chair position. Standard diagnostic arthroscopy will be performed. The capsulolabral complex will be freed from the anterior aspect of the scapular neck. The anterior aspect of the scapular neck will be decorticated using a motorized burr. A capsuloligamentous repair will be performed with the capsule shifted from inferior to superior and repaired on the glenoid face. The number of anchors used for the repair will be left to the discretion of the surgeon (a minimum of 3 anchors recommended). Remplissage procedure will be performed at the discretion of the operating surgeon.
All participants will follow a standardized rehabilitation protocol following surgical intervention: Phase I: Immediate postop phase (0-6 weeks) in sling, Passive range of movement, Phase II: Active motion phase (5-8 weeks after surgery), Phase III: Strengthening phase (8-12 weeks after surgery), Phase IV: Advanced strengthening phase (12 weeks and beyond).

Non-surgical treatment (Control Group)
Type of sling and immobilization will be left to the discretion of the operating surgeon. Patients randomized to non-surgical treatment will begin early physical therapy (PT) immediately as per protocol (2 weeks after initial immobilization). All participants will follow a standardized 3 phase rehabilitation protocol following 2 weeks of immobilization.

Study burden and risks

Following the initial urgent management and relocation of a dislocated shoulder, the prevention of recurrent instability is the critical management consideration for health care providers and surgeons. Two initial management options exist in patients with a FTD: non-operative care or surgical stabilization.
Recent research and available evidence over the past 10 years have called into question the role of a delayed approach to managing FTDs for a number of reasons. Surgical management has been suggested as a more reliable option to prevent further dislocations and improve patient outcomes when compared with non-operative management. Arthroscopic soft tissue repair (Bankart repair) has become increasingly popular given advancements in surgical technique allowing for a minimally invasive and reliable improvement in shoulder stability with a low risk of complication. The high recurrence rate in younger patients may justify offering surgical treatment after the first dislocation episode. A recent systematic review by Hurley et al.16 found arthroscopic Bankart repair resulted in a 7-fold lower recurrence rate and a higher rate of return to sport and activity than non-operative management21. While other surgical stabilization options exist, including non-anatomic bony transfer (Latarjet procedure), the Bankart repair is widespread as it is minimally invasive and restores native anatomy. Recent data also suggests that patients who are surgically treated following a FTD have improved outcomes when compared to those who have recurrent instability events before undergoing surgery. Delayed management of shoulder instability results in further injury to the shoulder joint. MRI evaluation of individuals who were assessed greater than 6 months from the time of initial dislocation had increased prevalence of not only recurrent shoulder instability events but a greater incidence and severity of intra-articular injury, including SLAP tears, labral tears, and glenoid cartilage damage.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patients ages 18-40 years;
2. Diagnosis of first-time anterior shoulder dislocation having occurred within the past 3 months, confirmed either by radiographic evidence or documented reduction of anterior shoulder dislocation as well as physical examination eliciting unwanted glenohumeral translation with reproduction of symptoms;
3. Provision of informed consent.

Exclusion criteria

1. Patients that cannot undergo surgery or anesthesia;
2. Patients with concomitant injuries (rotator cuff tear, fracture);
3. Previous shoulder surgery;
4. Patients that will likely have problems with maintaining follow-up or are incarcerated;
5. Epilepsy/seizure disorder
6. Pregnancy;
7. Diagnosis of multidirectional instability;
8. Bony glenoid defect (bony Bankart) >10% as measured on preop imaging;
9. Dislocation without trauma, in a context of hyper laxity or atraumatic instability;
10. Cases involving litigation or workplace insurance claims (e.g. WSIB).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT05715021
CCMO	NL86808.100.24