# Shoulder instability Trial comparing Arthroscopic stabilization Benefits compared with Latarjet procedure Evaluation (STABLE)

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Prior to large trial, we will conduct a pilot trial comparing compare arthroscopic capsuloligamentous repair vs. coracoid transfer (Latarjet procedure) on recurrent dislocation rates and functional outcomes over a 24-month period.Primary questionsWe…

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

## Summary

### ID

NL-OMON50962

**Source**
ToetsingOnline

**Brief title**
STABLE

### Condition

- Joint disorders

**Synonym**
Shoulder dislocation, Shoulder instability

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** McMaster University, department of Surgery

**Source(s) of monetary or material Support:** McMaster University Surgical Associates (MSA);Canadian Orthopaedic Research Legacy (CORL);Canadian Academy of Sport and Exercise Medicine (CASEM);Arthrex and Physicians Services Incorporated (PSI)

## Intervention

**Keyword:** Bankart, Latarjet, Shoulder dislocation

## Outcome measures

### Primary outcome

The primary outcome of the pilot study will be a composite measure of

feasibility, including:

1) Recruitment (number of patients recruited at each site during a 10-month

period),

2) Protocol adherence (number of errors in randomization); and

3) Follow-up (proportion of participants followed at two years).

We hypothesize that our feasibility outcomes will meet a priori criteria

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

thresholds:

1) 82 patients recruited within 10 months,

2) 3 or fewer errors in randomization across the 82 enrolled patients and

treatment adherence in a minimum 66 of 82 participants (80%), and

3) 70 of 82 participants (85%) achieving complete follow-up at two years.

### Secondary outcome

Secondary objectives are to evaluate:

1) Rate of recurrent dislocation and symptomatic instability between patients

randomized to (capsuloligamentous repair +/- remplissage) and those receiving open Latarjet procedure. This outcome is critically patient important and is objectively documented in the case of shoulder dislocation or in the case of recurrent symptomatic instability will be patient reported at follow up.

2) Clinical outcomes measured by Western Ontario Shoulder Instability (WOSI) Index, American Shoulder and Elbow Society (ASES) score, Patient Satisfaction Scale, Shoulder Activity Scale and EQ-5D;,

The WOSI is a self-administered quality of life outcome measure designed for clinical trials evaluating treatments for patients with shoulder instability.

It has been shown to have high reliability, validity and responsiveness31. The WOSI score is commonly utilized and has been shown to provide excellent ability to detect variability in severity of post-operative instability symptoms including following shoulder stabilization procedures30.

The ASES score is designed to assess shoulder function including instability29.

It allows for patient self-evaluation through 11 items that can be used to generate a score, divided into 2 areas: pain (1 item) and function (10 items).

Functional outcome assessment will be patient reported on paper through post-operative follow up forms administered by the study coordinator or designate at each site.

3) Physical examination: range of motion, strength, stability;

Physical examination following surgery will be performed by the operating surgeon and will consist of functional assessment important to patients. Range

of motion and strength as well as assessment of shoulder stability are commonly reported outcome measures in the literature when assessing success following shoulder instability surgery1,38. Range of motion will be assessed in forward flexion, abduction, external rotation and internal rotation.

Strength will be assessed on a five-point scale 0/5: no contraction, 1/5: muscle flicker, but no movement, 2/5: movement possible, but not against gravity (test the joint in its horizontal plane), 3/5: movement possible against gravity, but not against resistance by the examiner, 4/5: movement possible against some resistance by the examiner and 5/5: normal strength.

Stability will be assessed primarily via the apprehension- relocation physical examination maneuver which has demonstrated the highest sensitivity in the literature for the diagnosis of anterior instability.

4) Return to previous level of activity and sport

The majority of shoulder instability affects young individuals involved in athletic activities and sport. An important aspect in the success of surgical intervention is to return patients back to previous and desired level of activity6. This outcome will be patient reported at follow up.

5) Rate of major and minor shoulder-related complications and serious adverse events

Major complications will include, symptomatic non-union of transferred bone block, hardware penetration into the joint, neurological or vascular injury or

deep vein thrombosis.

# Study description

### Background summary

The shoulder is the most commonly dislocated joint in the body with a global incidence that ranges from 15.3 to 24.8 per 100 000 people. A review of shoulder reductions performed in emergency rooms in Ontario, Canada between 2002 and 2010 identified 20,719 dislocations affecting primarily young patients with a median age of 35 years and 74% male. Anterior dislocations, the most common type of shoulder dislocation, are often complicated by subsequent instability, and recurrent dislocation, with reported rates as high as 42% and primarily affecting young males. Shoulder instability commonly results in pain and negatively impacts quality of life.

During the process of a shoulder dislocation the anterior labrum attachment to the glenoid is commonly avulsed in what is known as a Bankart lesion. With recurrent dislocations there may be attrition of the labrum and progressive loss of the anterior bony contour of the glenoid. In instances where bone loss is not present the labrum is reattached to the glenoid in what is known as a Bankart repair which is commonly performed via open or arthroscopic means. Instances of significant bone loss (>25%) are commonly treated with a bone transfer known as a *Latarjet* procedure. There is controversy however regarding the optimal treatment of patients with some mild degree of bone loss.

### Study objective

Prior to large trial, we will conduct a pilot trial comparing compare arthroscopic capsuloligamentous repair vs. coracoid transfer (Latarjet procedure) on recurrent dislocation rates and functional outcomes over a 24-month period.

Primary questions
We aim to examine in a pilot RCT, the feasibility of a larger trial.
Feasibility objectives include:
1. Ability to recruit patients across clinical sites
2. Adherence to the study protocol; and
3. Ability to follow patients to 24 months

Secondary questions
Our trial will compare arthroscopic capsuloligamentous repair vs. coracoid transfer (Latarjet procedure) on:
1. Rates of recurrent shoulder dislocations and symptoms of instability up to

24 months* post- surgery;
2. Clinical outcomes measured by Western Ontario Shoulder Instability (WOSI) Index, American Shoulder and Elbow Society (ASES) score, Shoulder Activity Scale and EQ-5D and Patient Satisfaction Scale;
3. Physical examination: range of motion, strength, stability;
4. Return to previous level of activity;
5. Rate of shoulder-related complications and serious adverse events.

### Study design

We propose a multi-centre pilot RCT of 82 patients across Canada, United States and/or Europe to compare the effect of capsuloligamentous repair (Bankart procedure+ Remplissage) and coracoid transfer (Latarjet procedure) in patients with post-traumatic recurrent anterior dislocation. Eligible and consenting participants will be followed-up by the site for 24 months. Outcomes will be assessed at 2 weeks, 3 months, 6 months, 12 months, and 24 months post-surgery.

### Intervention

Participants will undergo arthroscopic stabilization (capsuloligamentous repair +/- remplissage) or open or arthroscopic Latarjet procedure according to standard procedure.

### Study burden and risks

Both the intervention and the control treatment as well as the x-ray taken after Latarjet procedure are standard care, therefore not associated with additional risks.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

1. Men and women ages 18-50 years;
2. Diagnosis of post-traumatic recurrent anterior dislocation. This will require a minimum of 2 episodes of documented dislocations 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. Mild glenoid bone loss as defined on CT by standardized and reproducible best-fit circle technique (>10% but <20%);
4. Provision of informed consent.

## Exclusion criteria

1. Patients with concomitant injuries (cuff tear);
2. Previous shoulder surgery;
3. Patients that will likely have problems, in the judgment of the investigators, with maintaining follow-up;
4. Epilepsy;
5. Patients who are or at risk of being incarcerated;
6. Diagnosis of multidirectional instability;
7. Cases involving litigation or workplace insurance claims (e.g. WSIB);
8. Confirmed connective tissue disorder (Ehlers-Danlos, Marfans) or Beighton hypermobility score >6.
9. Pregnancy.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2021 |
| Enrollment: | 20 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 26-07-2022 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 08-12-2022 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NCT03585491 |
| CCMO | NL76934.075.21 |