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Comparing the effectiveness of repair surgery methods (open Latarjet and arthroscopic Bankart) in treating recurrent shoulder dislocations

Submission date
26/11/2018

Recruitment status
No longer recruiting

Registration date
29/11/2019

Overall study status
Completed

Last Edited
10/09/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Shoulder instability after a trauma is the abnormal movement with an increased translation between the bones during its regular movement.
It is common to find associated lesions when there is instability and recurrent dislocations such as bone lesions in the head of the humerus and/or lesions in a part of the scapula (glenoid). This condition usually leads to a very important loss of the shoulder function, which causes a considerable negative influence in patient's activities of daily life. Some surgeries can provide stabilization of the joint to treat this condition.
One is the correction of the lesion in the glenoid using arthroscopy and other is open using another part of the scapula (coracoid process) in order to provide a bone block. As we can not find in the literature which is the best technique to treat shoulder instability, we aim to perform a study to compare both techniques. The best study design is a randomized controlled trial

Who can participate?
Patients aged from 18 to 40 years old with one or more episodes of shoulder dislocation

What does the study involve?
Participants will be randomly assigned to undergo one of the procedures described above and will be followed up regularly for one year

What are the possible benefits and risks of participating?
There is no risk or discomfort beyond what is expected in the treatment of anterior shoulder instability. (Examples of risks inherent in treating anterior shoulder instability: anesthetic risk, discomfort from immobilizer use, pain at the surgical site, infection, recurrence of instability).

Where is the study run from?
The Hand and Upper Limb Surgery Institute of the Orthopaedics and Traumatology Department of Universidade Federal de São Paulo, Brazil

When is the study starting and how long is it expected to run for?
November 2018 to February 2023

Who is funding the study?
1. Hand and Upper Member Discipline of São Paulo Federal University, Brazil
2. Sintegra, Brazil

Who is the main contact?
Prof. Rubens Guilherme Gonçalves
profrubensguilherme@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Rubens Guilherme Gonçalves

ORCID ID
http://orcid.org/0000-0002-2876-1210

Contact details
R. Borges Lagoa, 778
Vila Clementino
São Paulo
Brazil
04038-030
+55 11 55717106
profrubensguilherme@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
76bankartlatarjetrct

Study information

Scientific Title
Open Latarjet versus arthroscopic Bankart for anterior traumatic shoulder instability considering the shoulder function: randomized clinical trial

Acronym
TEBALARCT

Study objectives
The arthroscopic Bankart repair is as good as the Latarjet open procedure but with fewer complications, during the first six months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/04/2019, The Ethics Committee of the Universidade Federal de São Paulo/Hospital São Paulo (CEP/UNIFESP) (Rua Francisco de Castro, 55, Vila Clementino, São Paulo, 04020-050, Brazil; cep@unifesp.edu.br; +55 11 55711062), ref. 0038/2019

Study design
Single centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Traumatic anterior instability of the shoulder

Interventions
The two interventions are arthroscopic bankart repair and open latarjet. Patients will be divided into two randomized groups of 60 people each.

Randomisation and allocation
The randomisation sequence will be generated by computer software (http://www.randomizer.org), creating a list from 1 to 120, each number being related to one of the two proposed methods of treatment. We will perform simple (unrestricted) randomisation, making the intervention assignment unpredictable, including the last 10 participants. According to this list, inside each of the 120 opaque sealed envelopes numbered from 1 to 120, will be a piece of paper containing the words ‘Latarjet’ or ‘Bankart’.

Participant allocation will be performed after explaining the protocol and describing both of the procedures to be randomised, and after participants have agreed to take part and signed the informed consent form. They will also be clinically evaluated to determine whether they are suitable candidates for surgery. After this, an independent person will open the envelope before proceeding to the intervention

Intervention methods
Open Latarjet
Patients randomized to open Latarjet procedure will undergo preoperative evaluation of age, clinical condition and co-morbidities. The intervention will take place in the surgical centre of the institution, where four previously-specified surgeons, who are experienced with the surgical technique described by Walch and Edwards, will perform the surgical procedures. After the anaesthetic procedure, the patient will be kept in the 'beach chair' position and a small pillow will be placed behind the scapula to position the glenoid surface perpendicular to the operative table. After all, a deltopectoral approach will be made, with a 4 to 7 cm skin incision beginning under the tip of the coracoid process, retracting the cephalic vein laterally with the deltoid. The patient´s arm will be positioned in 90 degrees of abduction and external rotation, and the coracoacromial ligament will be sectioned 1 cm from the coracoid and the coracohumeral ligament will be released from the lateral part of the coracoid. After all, the arm will be adducted and internally rotated to release the pectoralis minor insertion from the coracoid and to expose the base of the coracoid with a periosteal elevator to allow observation of the "knee" of the coracoid process. Then, the coracoid process will be osteotomized with the use of an osteotome or a small angulated saw at the junction of the horizontal-vertical parts. The bone graft will be released from its deep attachments and decorticated. Then, two parallels holes will be made with a 3.2 mm drill. Two maleolar screws will then be placed securing the boné block to the glenoid. The arm will be moved through all ranges of motion to evaluate mobility, and then superficial soft-tissue layers will be closed.

Arthroscopic Bankart Repair
The surgical procedure will be performed with the patient in the lateral decubitus position. An arthroscopic suture passer will be used used to suture the labrum around the edge of the glenoid cavity with absorbable anchors, loaded with number 2 ethibond from 5 mm of the edge of the glenoid cavity. At least 3 anchors will be used in each procedure.

Treatment after the intervention
All patients will be advised to wear a sling for total restriction of external rotation and abduction. All the patients will be rehabilitated according to the same protocol.

The total duration and follow-up for both study arms will be the same:
- First week after surgery
- Second week after surgery
- Sixth week after surgery
- Twelfth week after surgery
- Twenty-fourth after surgery
- One year after surgery

Intervention Type
Procedure/Surgery

Primary outcome measure

The Western Ontario Shoulder Instability Index (WOSI) will be measured using questionnaire at the hospital admission on the day of the surgery, then on the sixth, twelfth, twenty-fourth weeks and one year after the procedure

Secondary outcome measures
At the hospital admission on the day of the surgery, then on the first, second, sixth, twelfth, twenty-fourth weeks and one year after the procedure:
1. Pain measured using the Visual Analog Scale (VAS)
2. Constant Score will be measured using questionnaire
3. ROM (The measurement will be made using a universal goniometer. Elevation will be measured in the scapular plane and active lateral rotation in the chest plane by means of pre and postoperative descriptive variables, comparing them with each other. Active medial rotation was assessed before and after surgery, using as a model part of the CONSTANT functional assessment scale, which divided the assessment of medial rotation on a scale from zero to ten, where zero is characterized as lateral side of the thigh and ten the interscapular region corresponding to the seventh thoracic vertebra)
4. Radiographic outcomes (implant loosening; Resorption of bone graft; articular congruence etc.) will be measured reviewing patient notes
5. Complications will be measured reviewing patient notes
6. Instability recurrence will be measured reviewing patient notes
7. Failure (which will be defined as a new joint incongruence without any traumatic or any other event not defined at the randomization)

Overall study start date
01/11/2018

Completion date
10/02/2023

Eligibility

Key inclusion criteria
1. Aged 18 to 40 years old
2. One or more episodes of shoulder dislocation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Previous anterior surgeries on the affected shoulder
2. Glenoid bone loss of more than 20%
3. Complete tear of rotator cuff
4. Voluntary dislocation of the shoulder
5. History of seizures
6. High risk of anaesthesiology-associated problems
7. On-track shoulder lesion

Date of first enrolment
01/03/2020

Date of final enrolment
10/02/2022

Locations

Countries of recruitment
Brazil

Study participating centre
Casa Da Mão EPM/UNIFESP
Rua Borges Lagoa, 778
Vila Clementino
São Paulo
Brazil
04038-030

Sponsor information

Organisation
Universidade Federal de São Paulo/Casa da Mmão

Sponsor details
Borges Lagoa street, 778
São Paulo
Brazil
04038-030

Sponsor type
University/education

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
University/education

Funder Name
Hand and Upper Member Discipline of São Paulo Federal University

Funder Name
Sintegra

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Mendeley) for 5 years after the end of the study. The data will be shared with researchers from universities which study the same topic, once the participants (patients) agree with this point

IPD sharing plan summary
Stored in repository