

J-bone graft versus Latarjet

Submission date 09/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/03/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/02/2021	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dislocations are joint injuries that force the ends of the bones out of position. There are two standardized and widely used operations to stabilize the shoulders of patients with multiple anterior shoulder dislocations. One technique is the Latarjet procedure and the other is the J-bone graft technique. The aim of this study is to investigate the clinical and radiological outcomes of patients after these two operations and in the long term to detect any differences in the occurrence of osteoarthritis.

Who can participate?

Patients aged 18-65 with post-traumatic recurrent anterior shoulder instability.

What does the study involve?

Participants complete questionnaires and undergo a physical examination, x-rays of both shoulders, and a CT scan before surgery. They are then randomly allocated to one of the two operations. After surgery another CT scan is performed. In addition all participants are asked to fill out questionnaires at 6, 12 and 24 months after surgery. At 12 and 24 months another CT scan is performed to investigate the affected shoulders. 5 and 10 years after surgery the participants are invited to fill out the questionnaires again and x-rays of both shoulders are taken in order to check for early onset osteoarthritis.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Department of Traumatology and Sports Injuries of the Paracelsus Medical University in Salzburg, Austria, and the Department for Shoulder and Elbow Surgery of the Atos Clinic in Munich, Germany.

When is the study starting and how long is it expected to run for?

March 2012 to March 2024.

Who is funding the study?

Department of Traumatology and Sports Injuries of the Paracelsus Medical University in Salzburg, Austria.

Who is the main contact?
Dr Philipp Moroder

Contact information

Type(s)
Scientific

Contact name
Dr Philipp Moroder

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5020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Clinical outcomes and osseous remodeling in Latarjet and J-bone grafting for post-traumatic recurrent anterior shoulder instability: a prospective randomized controlled trial with blinded outcome assessment

Study objectives
The clinical outcome of patients treated with a J-bone graft for post-traumatic recurrent anterior shoulder instability prevails over the outcome in patients receiving a Latarjet procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for the province of Salzburg (Ethikkommission für das Bundesland Salzburg), 08/02/2012, ref: 415-E/1439/5-2012

Study design
Multicenter prospective randomized controlled trial with blinded outcome assessment

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Post-traumatic recurrent anterior shoulder instability with significant glenoid defect

Interventions

Latarjet procedure according to Young et al. (JSES 2011) using the Arthrex Latarjet set, immobilization in a shoulder sling, physiotherapy, follow up at 6 months, 12 months, 24 months, 5 years and 10 years

J-bone graft procedure according to Auffarth et al. (AJSM 2008), immobilization in a shoulder sling, physiotherapy, follow up at 6 months, 12 months, 24 months, 5 years and 10 years

Intervention Type

Procedure/Surgery

Primary outcome measure

The clinical outcome at 6 months, 12 months, 24 months, 5 years, and 10 years measured using the Western Ontario Shoulder Instability Index of patients treated with a J-bone graft or Latarjet procedure for post-traumatic recurrent anterior shoulder instability with significant glenoid defect

Secondary outcome measures

1. The resorption/remodeling of both graft types is compared using pre-operative, post-operative, 12-months and 24 months post-operative CT imaging
2. The clinical outcome at 6 months, 12 months, 24 months, 5 years, and 10 years measured using the Subjective Shoulder Value of patients treated with a J-bone graft or Latarjet procedure for recurrent anterior shoulder instability
3. The clinical outcome at 6 months, 12 months, 24 months, 5 years, and 10 years measured using the Rowe Score and range of motion of patients treated with a J-bone graft or Latarjet procedure for recurrent anterior shoulder instability
4. Radiological assessment of osteoarthritic changes in the operated joint compared to the contra-lateral joint by bi-plane radiography of both shoulders at 5 years and 10 years follow up compared to the base-line images of both shoulders

Overall study start date

01/03/2012

Completion date

01/03/2024

Eligibility

Key inclusion criteria

1. Female or male patient of age 18-65 diagnosed with post-traumatic recurrent anterior shoulder instability and significant bony glenoid defect (15-30% of the glenoid surface area)
2. Obtained written consent from the patient

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

60

Total final enrolment

60

Key exclusion criteria

1. Patient prefers one surgical technique over the other or does not consent to a surgical treatment at all
2. Pre-existing ipsilateral shoulder pathology
3. Previous ipsilateral shoulder surgery except open or arthroscopic Bankart repair
4. Infection
5. Neuro-muscular disease
6. Lack of compliance
7. Problems with attending the regular follow-ups
8. Chronic alcohol or drug abuse

Date of first enrolment

01/03/2012

Date of final enrolment

01/03/2014

Locations

Countries of recruitment

Austria

Study participating centre

Muellner Hauptstraße 48

Salzburg

Austria

5020

Sponsor information

Organisation

Paracelsus Medical University (Austria)

Sponsor details

Department of Traumatology and Sports Injuries

Muellner Hauptstraße 48

Salzburg

Austria

5020

Sponsor type

University/education

ROR

<https://ror.org/03z3mg085>

Funder(s)

Funder type

University/education

Funder Name

Department of Traumatology and Sports Injuries, Paracelsus Medical University, Salzburg (Austria)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2019	15/02/2021	Yes	No