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# J-bone graft versus Latarjet

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 09/02/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 05/03/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 15/02/2021 | Injury, Occupational Diseases, Poisoning | |

## 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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Muellner Hauptstraße 48
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# 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 paient 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 |