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Open surgery versus arthroscopy for treating traumatic instability of the shoulder in adults

Submission date	Recruitment status
29/06/2010	No longer recruiting
Registration date	**Overall study status**
06/08/2010	Completed
Last Edited	**Condition category**
30/10/2012	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Repair of Bankart lesion in traumatic anterior shoulder instability: open surgery versus arthroscopic technique - a randomised controlled trial

Study objectives
There is no difference between open versus arthroscopic interventions for treating traumatic anterior shoulder instability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Universidade Federal de São Paulo/Hospital São Paulo approved in August 2003 (ref: CEP 0901/03 UNIFESP)

Study design
Randomised active controlled parallel group clinical 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 below to request a patient information sheet

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

Interventions
After arthroscopic examination, participants were randomised to:
1. Open surgery
2. Arthroscopic surgery

Total duration of treatment was approximately 1 hour for open surgery and 1 hour for arthroscopy. Total duration of follow-up was from 20 to 56 months for open surgery and from 18 to 56 months for arthroscopy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Disability of Arm Shoulder and Hand (DASH) Questionnaire
2. UCLA Shoulder Rating Scale
3. Rowe Score for Instability

Identical care program for rehabilitation was done in each of compared groups. Following enrolment in the study, all the participants were assessed every week during the first 2 weeks and at the 4th and 8th weeks; thereafter, monthly until the final examination. All primary and secondary outcomes were reported.

Secondary outcome measures
Range of movement: passive range of motion measurements, specifically forward flexion and internal and external rotation at 90° of abduction, were recorded and compared with the patients' nonoperative side.

Identical care program for rehabilitation was done in each of compared groups. Following enrolment in the study, all the participants were assessed every week during the first 2 weeks and at the 4th and 8th weeks; thereafter, monthly until the final examination. All primary and secondary outcomes were reported.

Overall study start date
01/11/2003

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Adults aged 18 - 40 years, either sex
2. Radiographic confirmation of a first-time anterior shoulder dislocation caused by an external force applied to the shoulder in a fall, or other forceful injury
3. No associated fracture visible on conventional radiographs at the time of presentation
4. Clinical history and symptoms of anterior shoulder instability
5. No medical contraindications to general anaesthesia
6. Detection of a Bankart lesion (anteroinferior capsulolabral detachment) on the arthroscopic examination of the shoulder

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
50 participants

Key exclusion criteria
1. Aged under 18 or over 40 years
2. Patients with generalised joint laxity, bilateral instability, multidirectional instability, and an additional soft-tissue injury that could affect joint stability
3. Patients with convulsive disorders, collagen diseases, previous surgery of the shoulder and any other condition that affects the shoulder mobility
4. Cerebrovascular disease or other severe medical illness
5. Inability to give informed consent or to complete questionnaires

Date of first enrolment
01/11/2003

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Brazil

Study participating centre
Department of Orthopaedics and Traumatology,
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Sponsor information

Organisation
Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00bkgf580

Funder(s)

Funder type
University/education

Funder Name
Universidade Federal de Sao Paulo (UNIFESP) (Brazil)

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	01/07/2012		Yes	No