ISRCTN47376242 https://doi.org/10.1186/ISRCTN47376242

Comparison of the results of operative versus non-operative management of acute grade III and IV acromioclavicular joint disruption

Submission date
15/06/2013

Recruitment status
No longer recruiting

Registration date
07/11/2013

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Injuries to the shoulder joint are common and often result in long-term pain, reduced function and an unsightly deformity over the shoulder. It is widely accepted that sprains and minor disclocations of the shoulder joint are best treated conservatively, but there is growing debate about the most appropriate treatment of complete dislocations. The aim of this study is to compare the results of non-operative and operative treatment for complete shoulder joint dislocations to guide future treatment.

Who can participate?
Men and women aged 16-35 years who have sustained a complete dislocation of the shoulder joint within the last two weeks

What does the study involve?
Participants are randomly allocated to one of two groups. Those allocated to the non-operative group are treated with an initial three-week period of immobilisation in a collar and cuff followed by physiotherapy. Participants allocated to the operative treatment group undergo surgery to stabilise the joint within two weeks of injury. The procedure is done through the open or keyhole method and involves reconstruction of the injured ligaments around the injured joint. After surgery, patients are then treated with immobilisation in a collar and cuff for three weeks followed by physiotherapy. All patients are seen at three weeks, six weeks, three months, six months and one year, when they may be asked to complete a questionnaire and undergo an examination. X-rays are also routinely taken during return visits.

What are the possible benefits and risks of participating?
The major benefit of having surgery is that they have a stable shoulder joint after the surgery, with less of a visible bump. This may allow an earlier return to work and sports. All the surgical procedures are performed under general anaesthetic. Although anaesthesia is extremely safe with modern techniques, there are still very small risks involved. Some patients experience nausea, vomiting and/or dizziness. These are reduced with modern drugs. It is important that participants tell the research team about any medical problems. For those that are allocated to

have an operation, the main risk is that the surgery fails to stabilise the injured joint and further instability is experienced (5% risk). There is a small chance of developing wound infection. This may require treatment with antibiotics. There is also a small risk of damage to the adjacent nerves and vessels in the shoulder.

Where is the study run from?
The study is being run from multiple orthopaedic centres who are experienced in both the management of these injuries and conducting studies of this kind including:
1. The Royal Infirmary of Edinburgh (UK) (main centre)
2. Glasgow Victoria Hospital (UK)
3. Glasgow Western Infirmary (UK)
4. Glasgow Royal Infirmary (UK)

When is study starting and how long is it expected to run for?
February 2011 to September 2015

Who is funding the study?
Arthrex (USA)

Who is the main contact?
Mr C M Robinson
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
10/S1101/55

Study information

Scientific Title

A multicentre prospective randomised controlled trial to compare the results of AcromioClavicular Open Reduction versus Nonoperative treatment for the management of acute grade III and IV acromioclavicular joint disruption

Acronym
ACORN

Study objectives
Operative management will not improve the functional outcome over non-operative management for acute grade III and IV acromioclavicular joint disruption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Research Ethics Committee, ref: 10/S1101/55

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Orthopaedic trauma

Interventions
A total of 80 participants will be randomised using the closed envelope technique into a control (non-operative management) group or treatment (operative management) group each containing 40 participants. All patients will be initially evaluated with a complete history and physical examination. Information regarding the mode of injury and timing of initial symptoms, any previous surgical procedures performed, and current type, level and frequency of symptoms including pain, instability and level of function will be specifically sought in addition to routine demographic details. Preoperative imaging including standardised plain film evaluation of the affected shoulder will be taken.

Control group: non-operative management
Following randomisation into the control group, participants will be treated with immobilisation in a collar and cuff for three weeks. Patients will return for clinical assessment 3 weeks following initial injury and will then begin a course of physiotherapy. Further clinical assessments will be scheduled at 6 weeks, 3 months, 6 months and 12 months.

Treatment group: operative treatment
Following randomisation into the treatment group, participants will be undergo open stabilisation with coracoclavicular ligamentous substitution within two weeks of the initial injury.

Open stabilisation with coracoclavicular ligamentous substitution
The following steps will performed through an open approach. The disrupted acromioclavicular joint will be visualized and reduced with no excision of lateral clavicle or acrion. Repair of existing acromioclavicular and coracoclavicular ligaments will be performed. Stabilization will be achieved using the AC-Tightrope Technique, with the Tightrope spanning between the coracoid and lateral clavicle. In all centres, the operative procedure will be carried out by a specialist shoulder surgeon. The potential risks of operative stabilisation will be explained by the operating surgeon. These include risk of recurrent instability (5%), infection (1%) and death under general anaesthetic (1 in 200,000).

Postoperative protocol and follow-up
Patients will be immobilised for 3 weeks postoperatively in a collar and cuff. These patients will be routinely discharged on day 1 postoperatively. Patients will return for clinical assessment 3 weeks following initial injury and will then begin a course of physiotherapy. Active strengthening will commence at 6 weeks. Further clinical assessments will be scheduled at 6 weeks, 3 months, 6 months and 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Functional assessment with use of the short-form health survey (SF-12), Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and Oxford score will be carried out for all patients preoperatively, at 6 weeks and at 12 months postoperatively. In addition SF-12 and DASH scores will be assessed at 3 and 6 months.

Key secondary outcome(s))
1. Shoulder ROM will be assessed at 6 months and 12 months postoperatively. The contralateral shoulder will be assessed for comparison
2. Any complications occurring in patients in either group will be documented at the time of procedure and throughout follow-up
3. Radiographic evidence of recurrent dislocation

Completion date
01/09/2015

Eligibility

Key inclusion criteria
1. Grade III or IV acromioclavicular joint disruption
2. Acute injury (within last 2 weeks)
3. Age 16-35 years inclusive

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Grade I or II acromioclavicular joint disruptions
2. Patients who are not local residents and unable to attend for follow-up
3. Coexisting clavicle or proximal humeral fractures
4. Multiple medical co-morbidities

Date of first enrolment
01/02/2011

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Glasgow Victoria Hospital
United Kingdom
G42 9LF

Study participating centre
Glasgow Western Infirmary
United Kingdom
G11 6NT

Study participating centre
Glasgow Royal Infirmary
United Kingdom
G4 0SF

Sponsor information

Organisation
Royal Infirmary of Edinburgh (UK)

ROR
https://ror.org/009bsy196

Funder(s)

Funder type
Industry

Funder Name
Arthrex (USA)

Results and Publications

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	21/11/2018	15/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes