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Comparing the surgical and non-surgical treatment of acute shoulder joint dislocations

Submission date
20/06/2020

Recruitment status
No longer recruiting

Registration date
06/08/2020

Overall study status
Completed

Last Edited
01/09/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Acromioclavicular (shoulder) joint dislocations are common shoulder injuries and are classified according to Rockwood. Type 3 injuries are defined as complete separations with tearing of both ligaments. The current literature is in favour of non-surgical treatment of Rockwood type 3 injuries. However, larger series of high evidence dealing with isolated type 3 injuries are lacking. The aim of this study is to conduct a multicentre, randomized trial comparing non-surgical and surgical treatment. The hypothesis is that surgical treatment in acute ACJ dislocations type 3 outperforms non-surgical treatment in terms of functional outcome after a follow-up period of 2 years.

Who can participate?
Patients aged between 18 and 65 years suffering from an acute (within 3 weeks after the trauma) acromioclavicular joint dislocation Rockwood type 3.

What does the study involve?
The study involves regular radiological and clinical follow up evaluation at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months. Two treatment modalities are compared after randomized allocation of the study participants. The functional outcome of non-surgical and surgical treatment are evaluated using specific shoulder scores and the pain level is recorded at all timepoints. Radiological parameters are measured including the coracoclavicular distance and posttraumatic osteoarthritis or heterotopic ossifications.

What are the possible benefits and risks of participating?
All patients undergo standardized state of the art medical treatment when participating. Since the best treatment option for acute Rockwood type 3 injuries is still not determined, there is no benefit or risk of participating. After detailed information about kind of injury and possible treatment options patients are included after obtaining written informed consent.

Where is the study run from?
The study is allocated in 4 study centers. Three of them are located in Germany, one in Austria.

When is the study starting and how long is it expected to run for?
July 2010 to March 2018

Who is funding the study?
There is no outside funding of the study.

Who is the main contact?
Mark Tauber, MD
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
No difference between surgical and non-surgical treatment of acute acromioclavicular Rockwood type III injuries - a prospective, multicentric randomized trial

Study objectives
Surgical treatment in acute acromioclavicular joint (ACJ) dislocations Rockwood type III outperforms non-surgical treatment in terms of functional outcome after a follow-up (FU) period of 2 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2010, Salzburg Ethics Committee (Ethical Committe for Salzburg County, Michael-Pacher-Strasse 36 (EG, Zi.48), 5020 Salzburg, Austria; no telephone number provided; ethikkommission@salzburg.gv.at), ref: 1277

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute acromioclavicular joint dislocations Rockwood type 3

Interventions
Surgical versus non-surgical treatment of acute acromioclavicular joint dislocations Rockwood type 3 will be compared.
Non-surgical treatment includes adequate pain management using non-steroidal antirheumatics for several days, accompanied by local ice therapy and immobilization of the injured shoulder using a simple sling. Duration of immobilization is based on the patient’s pain level and lasts usually between 10 to 14 days. Physical rehabilitation measures are initiated under a physiotherapist’s guidance and continued until free ROM is achieved.
Surgical treatment includes 4 different surgical techniques, one for each study center. These are the hook plate (center 1), the Tight Rope device (Arthrex, Naples, FL, USA) implanted arthrscopically in a double fashion (center 2), in a single fashion (center 3) and mini-open in a double fashion (center 4).
The postoperative protocol is the same for all techniques including pain management, local ice therapy, and immobilization for 6 weeks in a simple sling. During this period only passive motion and exercises until 90° of glenohumeral abduction are allowed. Actively assisted shoulder motion in all planes follows for the next 6 weeks starting with shoulder sports after 4 months.

After obtaining the patients' written consent 1:1 allocation to either surgical or non-surgical treatment was performed by the treating surgeon at each center based on a pre-specified list generated by the principal investigator using a web-based internet randomizer [www.randomize.net].

Intervention Type
Procedure/Surgery

Primary outcome(s)
The functional outcome using the Constant score is measured at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months

Key secondary outcome(s))
Recovery measured using the following measures:
1. Pain measured using a numeric rating scale at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months
2. The Acromioclavicular Joint Injury Score measured at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months
3. The Taft score measured at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months
4. The American Shoulder and Elbow Surgeon's score measured at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months
5. The coracoclavicular distance (in milimeters) measured at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Presence of an acute (within 3 weeks after trauma) ACJ injury
2. ACJ dislocation type III according to the classification of Rockwood defined by an increase of the coracoclavicular distance of 25-100% compared to the contralateral side on a panorama stress-view with 10kg of load on the hanging arm
3. Aged between 18 and 65 years
4. Written informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Patient’s request for reconstruction out of cosmetic purposes
2. Pre-existing shoulder- or ACJ-related pathologies of the affected or contralateral shoulder
3. Acute or chronic infections of the involved joint
4. Neurological or musculoskeletal diseases affecting the shoulder
5. Inadequate compliance
6. Inability to participate in the regular FUs
7. Abuse of drugs or alcohol
8. Worker’s compensation claim

Date of first enrolment
01/01/2011

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
Austria

Germany

Study participating centre
ATOS clinic Munich
Effnerstrasse 38
Munich
Germany
81925

Study participating centre
University Clinic Charitè
Department of Orthopaedics and Trauma Surgery
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Study participating centre
University clinic Mannheim
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Study participating centre
University clinic Salzburg
Department of Orthopaedics and Trauma Surgery
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Sponsor information

Organisation
Paracelsus Medical University

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	version v1.0	25/08/2023	01/09/2023	Yes	No

Participant information sheet	06/08/2020	No	Yes