Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of the effect of surgical treatment of midshaft clavicle fracture with plate versus non operative treatment in imam Golestan and Razi hospital during 1390-1392

Protocol summary

Summary

The aim of this study is comparison of the effect of surgical treatment of midshaft clavicle fracture with plate versus non surgical treatment. In this study, 70 patients with fractures of the medial clavicle referred to the emergency ward of Razi and Emam hospitals, are enrolled into the study and after a thorough explanation about the complications of treatment are randomly assigned to 2 groups. The patients in two groups are matched for age, sex, and fracture type. Clinical and radiological evaluation and follow up will be done for 3 months until a full-time union. At the end of treatment DASH score questionnaire will be completed and the results of examinations and questionnaires in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061113633N1**
Registration date: **2013-07-14, 1392/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-14, 1392/04/23

Registrant information

Name

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Name of organization / entity

Ahwaz joundishapour university of medical sience

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Ahwaz Joundishapour University of Medical Siences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of surgical treatment of midshaft clavicle fracture with plate versus non operative treatment in imam Golestan and Razi hospital during 1390-1392

Public title

The comparison of the results of surgical and non surgical treatment of clavicle fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: fractured clavicle midshaft, age under 60 years old over 18 years Exclusion criteria: clavicular fractures elsewhere; ages under 18 years of age to 80 years.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahwaz Joundishapour University of Medical Siences
Street address
Ground Floor, Department of Research and Technology,City University
City
Ahvaz
Postal code
6135715794
Approval date
2013-03-09, 1391/12/19
Ethics committee reference number
139207

Health conditions studied

1

Description of health condition studied
Fracture of clavicle
ICD-10 code
S42.0
ICD-10 code description
Fracture of clavicle

Primary outcomes

1

Description
Union of clavicle fracture
Timepoint
Every 6 month
Method of measurement
Serial x Ray

2

Description
Physical function
Timepoint
Every 6 month
Method of measurement
Physical exam and DASH score

3

Description
Time to go back to work
Timepoint
Every 6 month
Method of measurement
Based on day

4

Description
Cost of treatment
Timepoint
Every 6 month
Method of measurement
Spending on Rials

5

Description
Restriction movement
Timepoint
Every 6 month
Method of measurement
Physical examination and calculation of shoulder joint range of motion

6

Description
Treatment duration
Timepoint
Every 6 month
Method of measurement
Full recovery by day

7

Description
Pain
Timepoint
Every 6 month
Method of measurement
History an functional score

Secondary outcomes

1

Description

Malunion of clavicle fracture
Timepoint
Every 6 month
Method of measurement
Serial x Ray

Intervention groups

1

Description
Clavicle fracture surgery
Category
Treatment - Surgery

2

Description
Non operative treatment of clavicle fracture
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahwaz Imam Khomeini Hospital, Emergency Orthopedics
Full name of responsible person
Resident on-call orthopedic
Street address
Azadegan Street, 24 meters away
City
Ahwaz

2

Recruitment center
Name of recruitment center
Razi Hospital, Emergency Orthopedics
Full name of responsible person
Resident on-call orthopedic
Street address
Palestine Street, opposite Government
City
Ahvaz

3

Recruitment center
Name of recruitment center
Golestan Hospital in Ahwaz
Full name of responsible person
Resident on-call orthopedic
Street address
Golestan St.
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Joundishapour University of Medical Sciences
Full name of responsible person
Doctor Mohammad Reza Abbaspoor
Street address
, Department of Research and Technology Developmen,City University
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Joundishapour University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz Joundishapour University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty