

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

To compare the results of internal fixation of midshaft clavicular fractures by pin and plate

Protocol summary

Summary

To compare the results of internal fixation of midshaft clavicular fractures by pin and plate. Design: a randomized controlled clinical trial. Patients: 50 cases (42 male and 8 female) with clavicular fractures will be assigned to two groups consist of 25 persons in each. Inclusion criteria will be: the age of 18 to 60 years, Fracture of clavicle. Exclusion criteria will be: Open fracture of clavicle, fracture and nerve damage in the same side of the upper limb. Intervention: we will operate the first patient with smooth 3.5 mm pin and the other with 3.5 mm plate and will continue the operations in the same manner. The patients will be followed up until complete union. Main outcomes: As long as 6 months follow-up, treatment results and complications of treatment with these two methods will be reviewed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105165920N3**
Registration date: **2011-06-07, 1390/03/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

Name

Sulmaz Natanj

Name of organization / entity

Jundishapour university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1336 2344

Email address

natanj.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Jundishapour University Of Medical Sciences

Expected recruitment start date

2008-09-02, 1387/06/12

Expected recruitment end date

2010-09-03, 1389/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the results of internal fixation of midshaft clavicular fractures by pin and plate

Public title

Surgical fixation of clavicular fracture in the appropriate field

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age of 18 to 60 years, Fracture of clavicle. Exclusion criteria: Open fracture of clavicle, fracture and nerve damage in the same side of the upper limb.

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: 50

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

Jundishapour University Of Medical Sciences

Street address

Golestan Blvrd

City

Ahvaz

Postal code

Approval date

2010-05-31, 1389/03/10

Ethics committee reference number

ETh005

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

Timepoint

4,6,8 weeks and 6 months postoperatively

Method of measurement

Using X ray of clavicle

2

Description

Shoulder Score

Timepoint

6 months postoperatively

Method of measurement

Using Shoulder Scores

Secondary outcomes

1

Description

Operation time

Timepoint

During surgery

Method of measurement

Based on surgery duration in minutes

2

Description

Bleeding

Timepoint

During surgery

Method of measurement

Based on the amount of intraoperative bleeding according ml

3

Description

Infection

Timepoint

2,4,6,8 weeks and 6 months postoperatively

Method of measurement

Based on clinical symptoms such as inflammation and purulent discharge from wounds or radiographic signs such as sequestrum

4

Description

Symptomatic hardware

Timepoint

6 months postoperatively

Method of measurement

Based on patient complaints

Intervention groups

1

Description

Internal fixation with pin

Category

Treatment - Surgery

2

Description

Internal fixation with plate

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Sharareh Shalamzari

Street address

Ahvaz Emam Khomeini hospital

City

Ahvaz

2

Recruitment center

Name of recruitment center

Ahvaz Emam Khomeini hospital

Full name of responsible person

Sharareh Shalamzari

Street address

Ahvaz Emam Khomeini hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi, Vice-Chancellor For Research

Street address

Vice-Chancellor For Research, Jundishapour University
Of Medical Sciences, Golestan Blvd

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Jundishapour 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**

Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Saaid Tabatabaei

Position

Assistant professor of orthopedic surgery

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Postal code**Phone****Fax****Email**

sh_shalamzari@yahoo.com

Web page address

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