

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigation of complications and results of clavicle fracture treatment using anterior plate or superior plate in patients referred to medical training centers of Isfahan University of Medical Sciences.

Protocol summary

Study aim

Determining and comparing the short and medium term effects of anterior and superior plate insertion in clavicle fracture

Design

The 52 patients from among the patients who met the inclusion criteria and did not meet the exclusion criteria and were admitted to medical training centers of the University of Medical Sciences were included in the study. Then they will be randomly assigned to each anterior plaque or superior plaque treatment group with the help of randomization software

Settings and conduct

Patients will surgery based on their grouping, which is done on a one-to-one basis and they are not aware of it. During the operation, 2 weeks, 1 month, 3 m and 6 m after the operation, they will go to the orthopedic clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clavicle fx 18 to 60 years Consent to participate study Non-entry criteria: multiple fx Open clavicle fx underlying disease such as malignancy and Pathological fx Previous clavicle fx synchronous vascular and nerve damage

Intervention groups

Patients are divided into 2 groups superior or anterior plate surgery, both methods were used in clavicle fx stabilization, but there is a debate about their superiority.

Main outcome variables

time of surgery Hospitalization period Shoulder ROM Examination of the sensation and movement of the fingers Union pain score infection The level of patient satisfaction with the position of the plaque based on the level of palpation under the skin Vascular and nerve damage during surgery Average time to return to daily life activities Cases requiring further surgery Delay Union

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230924059500N1**

Registration date: **2024-01-06, 1402/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-06, 1402/10/16**

Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

Name

Himan Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-26, 1402/10/05

Expected recruitment end date

2024-01-15, 1402/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of complications and results of clavicle fracture treatment using anterior plate or superior plate in patients referred to medical training centers of Isfahan University of Medical Sciences.

Public title

Investigating complications and results of clavicle fracture treatment using anterior plate or superior plate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clavicle fracture Age 18 to 60 years Consent to participate in the study

Exclusion criteria:

The presence of multiple fractures of other organs Open clavicle fracture The presence of an underlying disease such as malignancy and..Pathological fracture Previous clavicle fracture The simultaneous presence of vascular and nerve damage

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient will be given a full explanation of the procedure and conditions, and consent will be obtained to participate in the study, but the patient will not be informed about the position of the operation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hazarjarib Street; Isfahan University of Medical

Sciences

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Province

Isfahan

Postal code

8174673461

Approval date

2023-08-14, 1402/05/23

Ethics committee reference number

IR.MUI.MED.REC.1402.182

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

Postoperative pain

Timepoint

2 weeks after surgery, 1 month after, 3 months after and 6 months after surgery

Method of measurement

VAS Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Superior plate. these patients under go clavicle fracture surgery and reconstruction using a plate placed on the superior surface of the clavicle. all other surgical protocols and post surgical care are done using a standard care and surgery protocol for the patient.

Category

Treatment - Surgery

2

Description

Intervention group 2: Anterior plate. these patients under go clavicle fracture surgery and reconstruction using a plate placed on the antero inferior surface of the clavicle. all other surgical protocols and post surgical care are done using a standard care and surgery protocol for the patient.

Category

Treatment - Surgery

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mojtaba Baniyasi

Position

Assistant Professor

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available