

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparing clinical outcomes of clavicle fracture surgical treatment methods of fixation with two plates 2.7 millimeters and fixation with plate 3.5 millimeters

Protocol summary

Study aim

In this study, we will investigate the use of the double plate method for fixation of clavicle fractures and compare its complications and efficiency with the method of fixation with a single plate.

Design

A clinical trial with a control group, with parallel randomized groups, was used to assign numbers to patients based on random number table numbers for randomization.

Settings and conduct

The surgeon and the patient are aware of the methods of surgical treatment, but the person who performs the patients' functional measurements after surgery is blind to the type of surgical procedure of the patients.

Participants/Inclusion and exclusion criteria

Patients aged 18-60 years with a middle third clavicle fracture shortened or displaced by 2 centimeters or more are included in the study. Patients with open fractures, fractures with neurovascular damage, and internal and external one-third fractures, and patients with multiple injuries will be excluded.

Intervention groups

In our study, we will surgically fix the clavicle fractures of group A using two 2.7 millimeters(mm) plates and group B with a 3.5 mm plate.

Main outcome variables

Bleeding amount in surgery, surgery time, incision length, orthopedic classification of fractures, and the disabilities of the arm, shoulder and hand (DASH) questionnaire score are the main outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053235N1**

Registration date: **2021-12-19, 1400/09/28**

Registration timing: **prospective**

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Meisam Jafari Kafiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2271 8000

Email address

dr.jafari8567@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-21, 1400/09/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing clinical outcomes of clavicle fracture surgical treatment methods of fixation with two plates 2.7 millimeters and fixation with plate 3.5 millimeters

Public title

Clavicle fracture surgical methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mid-shaft clavicle fractures The fractures which are shortened or displaced by 2 centimeters or more

Exclusion criteria:

Distal third and medial clavicle fracture Patients with neurovascular problems due to clavicle fracture Patients with multiple traumas Patients with open fractures

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: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups by the simple randomization method based on the numbers assigned to them based on the table of random numbers.

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

Ethical Committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran, Iran

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Province

Tehran

Postal code

19839631113

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.518

Health conditions studied

1

Description of health condition studied

Patients with middle clavicle fractures

ICD-10 code

S42.00

ICD-10 code description

Fracture of clavicle, closed

Primary outcomes

1

Description

Patient's function based on the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire Score.

Timepoint

3 and 6 months after surgery

Method of measurement

Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with medial clavicle fracture to be treated with surgical fixation of two 2.7 millimeters fixation surgery

Category

Treatment - Surgery

2

Description

Control group: Patients with medial clavicle fracture to be treated with surgical fixation of one 3.5 millimeters plaque fixation surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shoda e Tajrish Hospital

Full name of responsible person

Meisam Jafari Kafiabadi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research affairs of Shahid Beheshti 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
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Meisam Jafari Kafiabadi
Position
Assistant professor
Latest degree
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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

The data documents will be available at the end of study

When the data will become available and for how long

The data documents will be available at the end of study.

To whom data/document is available

The data documents will be available at the end of study for academic researches

Under which criteria data/document could be used

Under request

From where data/document is obtainable

at the end of study

What processes are involved for a request to access data/document

sending emails

Comments