

# 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)

###### Phone

+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

**City**

Tehran

**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

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Shohada-e-Tajrish Hospital, Qods Sq., Tajrish, Tehran, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Dr. Afshin Zarghi  
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Arabi Ave, Daneshjoo Blvd., Velenjak, Tehran, Iran.  
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mpd@sbm.ac.ir  
**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**  
Specialist  
**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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**