

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Walant technique for clavicle fracture fixation with anatomic locking plate with diameter 3.5 millimeters

#### Protocol summary

##### Study aim

Evaluation of the results of using the walant technique in open surgery of clavicle fractures with the help of a plate with a diameter of 3.5 mm

##### Design

Phase 2 clinical trial in patients with acute clavicle fractures requiring fixation surgery that the control group does not have.

##### Settings and conduct

Included patients will be transferred to the operating room and first WALANT solution is injected for them and then the patients are transferred to the operating table and undergo surgery. The WALANT is 200 cc of a solution containing 50 ccs of 1% lidocaine and 5 ccs of 7.5% sodium bicarbonate, 1 cc of adrenaline, and normal saline.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 16 to 60 years with acute clavicle fractures require fixation surgery.  
Exclusion criteria are patients with cardiovascular problems or with a history of seizure and psychiatric problems, open fractures, fractures with vascular-neurological damage, and other serious injuries in the shoulder girdle.

##### Intervention groups

Patients aged 16 to 60 years with acute clavicle fractures require fixation surgery operated with open clavicle surgery with WALANT techniques ( wide awake local anesthesia no tourniquet)

##### Main outcome variables

During and after the operations, various factors such as pain, bleeding and range of motion, patient activity, and surgical complications are collected by a pre-prepared questionnaire. During the patient's hospitalization, we consider and follow the patient's bleeding volume and wound problems.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211201053235N2**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **prospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

##### Registration date

2022-01-27, 1400/11/07

##### 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

2022-02-05, 1400/11/16

##### Expected recruitment end date

2022-05-06, 1401/02/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Walant technique for clavicle fracture fixation with anatomic locking plate with diameter 3.5 millimeters

IR.SBMU.RETECH.REC.1400.764

## Public title

Open surgical treatment of clavicle fractures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Acute clavicle fracture requires fixation surgery

### Exclusion criteria:

Patients with cardiovascular problems Patients with history of seizure Patients with history of psychiatry disorders Patients with open clavicle fractures Fractures associated with vascular-neurological damage Serious injury to the shoulder girdle

## Age

From **16 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences, Yemen Street, Shahid Chamran Highway, Iran, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### Approval date

2022-01-09, 1400/10/19

#### Ethics committee reference number

## 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

Pain

#### Timepoint

2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery

#### Method of measurement

visual analogue scale

### 2

#### Description

bleeding volume during surgery

#### Timepoint

2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery

#### Method of measurement

Blood volume measurement

### 3

#### Description

union of bones

#### Timepoint

2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery

#### Method of measurement

Assessment of the bony cortex on radiography

### 4

#### Description

Duration of hospitalization

#### Timepoint

2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery

#### Method of measurement

Patients records

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Patients with open clavicle fracture surgery with the help of plaque with a diameter of 3.5 mm and anesthesia injection technique of 200 cc of solution containing 50 cc of 1% lidocaine and 5 cc of sodium bicarbonate 7.5%, 1 cc of adrenaline and normal saline

### Category

Treatment - Surgery

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shohada Tajrish Hospital

#### Full name of responsible person

Dr. Meisam Jafari Kafiabadi

#### Street address

Tajrish square

#### City

Tehran

#### Province

Tehran

#### Postal code

1989934148

#### Phone

+98 21 25719

#### Email

dr.jafari8567@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

Yemen street, Chamran highway, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1985717434

#### Phone

+98 21 2243 9951

#### Email

mpd@sbm.u.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

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

Orthopedics

#### Street address

Yemen street, Shahid Chamran highway

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#### Province

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#### Postal code

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#### Phone

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#### Email

dr.jafari8567@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Farsad Biglari

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Orthopedics

#### Street address

Yemen street, Chamran highway

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**Email**

biglari.farsad@gmail.com

**Person responsible for updating data****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**

Orthopedics

**Street address**

Shohada-e tejrish hospital, Tajrish, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Phone**

+98 21 2271 8000

**Fax****Email**

dr.jafari8567@yahoo.com

**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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After finishing patient recruitment

**When the data will become available and for how long**

After finishing patient recruitment

**To whom data/document is available**

After finishing patient recruitment

**Under which criteria data/document could be used**

After finishing patient recruitment

**From where data/document is obtainable**

After finishing patient recruitment

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

After finishing patient recruitment

**Comments**

After finishing patient recruitment