

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparison of the Postoperative Results, and complications of Both-bone Forearm Fractures Surgery with or without suction Drainages in 15 to 65 y/o patients

#### Protocol summary

##### Study aim

Comparison of treatment results and complications after forearm fracture surgery with and without drainage

##### Design

نتایج درمانی گذاشتن درن یا عدم استفاده از آن در دو گروه که پس از انجام معیارهای ورود و خروج به صورت تصادفی انتخاب میگردند، مقایسه خواهد شد.

##### Settings and conduct

After confirmation of the fracture using AP and lateral radiography of the forearm, elbow and wrist, patients in the operating room will undergo volar henry approach to fix the radius bone and lateral approach to fix the ulna bone with screws and plates. After surgery In one group of patients, a hemovac drain will be inserted into the wound, and in the other group, the drain will be implanted after proper blood hemostasis. All surgeries will be performed by one certain surgeon and surgical assistant (study researchers) in the orthopedic operating room of Shahid Bahonar in Kerman

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are patients aged 15 to 65 years old with closed fractures of the both bones of the forearm that require open reduction an internal fixation

##### Intervention groups

The therapeutic results of draining or not using it will be compared between the two groups.

##### Main outcome variables

In the two groups studied, the need for analgesia, infection, pain and bone union will be compared.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220619055220N1**  
Registration date: **2022-06-30, 1401/04/09**

Registration timing: **prospective**

Last update: **2022-06-30, 1401/04/09**

Update count: **0**

##### Registration date

2022-06-30, 1401/04/09

##### Registrant information

###### Name

Mohammadhadi Nateghi jahromi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5433 4568

###### Email address

hadi.nateghi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Postoperative Results, and complications of Both-bone Forearm Fractures Surgery with or without suction Drainages in 15 to 65 y/o patients

##### Public title

Comparison of the results of using a drain or not using it

in forearm fractures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Fractures of the forearm bone between the ages of 15 and 65 that require open reduction and internal fixation

### Exclusion criteria:

Open fractures as well as patients who have fractures in other organs

## Age

From **15 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **44**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization of patients will be done using quadruple random blocks, considering that the number of treatment methods is two methods (randomly one method is called A and the other method B). Possible blocks are AABB, ABAB, ABBA, BAAB, BABA and BBAA are. These blocks are also randomly selected and assigned to each method based on the sequence created by the patients.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, blinding is performed on the data analyzer

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of kerman University of Medical Sciences

##### Street address

shahid bahonar hospital, kerman

##### City

kerman

##### Province

Kerman

##### Postal code

7613747181

## Approval date

2022-06-18, 1401/03/28

## Ethics committee reference number

IR.KMU.AH.REC.1401.052

## Health conditions studied

### 1

#### Description of health condition studied

Forearm both bone fractures

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The rate of infection and union of the forearm bones.

#### Timepoint

During the first 48 hours, 2 weeks later, 6 weeks later, 3 months later and 6 months after surgery

#### Method of measurement

Patients' hemoglobin level before and after surgery using cbc test/Evaluation of patients' pain through visual analog score

## Secondary outcomes

### 1

#### Description

Comparison of patients' pain during 48 hours after surgery/Comparison of hemoglobin loss in two groups/Comparison of patients' pain based on visual analog scale/Comparison of bone union in two groups.

#### Timepoint

During the first 48 hours, 2 weeks later, 6 weeks later, 3 months later and 6 months later.

#### Method of measurement

CBC-based hemoglobin measurement of patients/The amount of discharge from the hemovac drain

## Intervention groups

### 1

#### Description

After confirmation of the fracture using AP and lateral radiographs of the forearm, elbow and wrist, patients in the operating room will undergo volar henry approach to fix the radius bone and lateral approach to fix the ulna bone with screws and plates. After he surgery will be completed in one In one group of patients, a hemovac drain will be inserted into the wound, and in the other group, after complete hemostasis the drain will not be implanted. All surgeries will be performed by a surgeon and surgical assistant (study researchers) in one operating room.

**Category**  
Treatment - Surgery

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
مرکز بیمارستانی شهید باهنر کرمان  
**Full name of responsible person**  
محمد هادی ناطقی جهرمی  
**Street address**  
shahid bahonar hospital,kerman  
**City**  
کرمان  
**Province**  
Kerman  
**Postal code**  
7613747181  
**Phone**  
+98 71 5433 4568  
**Email**  
hadi.nateghi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
mohammad hadi nateghi jahromi  
**Street address**  
shahid bahonar hospital,kerman  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7613747181  
**Phone**  
+98 71 5433 4568  
**Email**  
hadi.nateghi@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Kerman 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
dramirreza sadeghifar  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
shahid bahonar hospital,kerman  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7613747181  
**Phone**  
0098 32237115  
**Email**  
drsadeghifar2000@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
دکتر امیررضا صادقی فر  
**Position**  
دانشیار گروه ارتوپدی کرمان  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
shahid bahonar hospital,kerman  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7613747181  
**Phone**  
00 3432237115  
**Email**  
drsadeghifar2000@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**

dramirreza sadeghifar

**Position**

associated professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

**Street address**

shahid bahonar hospital,kerman

**City**

kerman

**Province**

Kerman

**Postal code**

7613747181

**Phone**

0098 32237115

**Email**

drsadeghifar2000@gmail.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**

All tests and measured patient variables will be available after the patients' personal information is not identifiable.

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

After gathering complete and documented information

**To whom data/document is available**

For researchers in medical centers

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

Requested data according to the approvals of the Medical Ethics Committee

**From where data/document is obtainable**

Medical ethics references of medical sciences

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

Refer to Medical Ethics Center of Medical Sciences

**Comments**