

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

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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
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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?

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
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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

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