

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of two methods of Fixation with a Plaque and Functional brace in The treatment of Humerus trunk fracture in Patients referred to Bahonar Hospital

Protocol summary

Study aim

Due to the high prevalence of Humerus fractures and dysfunction in patients with fractures and disagreement about the appropriate treatment method concerning the advantages and disadvantages of each surgical and non-surgical method in this study, the intention to achieve a standard method with high efficiency, time We have less treatment and shorter recovery in patients with Humerus trunk fractures.

Design

Divide patients into two groups and perform surgical intervention on one group and follow the other group with functional braces.

Settings and conduct

People who complain of Humerus shaft fracture to the emergency department of Shahid Bahonar Hospital in Kerman, are divided into two groups to assign people to two the group uses block randomization, one group is referred to the operating room and after the initial procedures, it is operated by sterile method and fixation with plaque is performed for them. The other group They are followed up in the emergency room by uslap and are discharged after one day with Sarminto functional brace.

Participants/Inclusion and exclusion criteria

Inclusion criteria include people 18 to 60 years of age, including adults with informed and written consent; Criteria for not including people below 18 or over 60 years old; patients with open wounds at the fracture site; patients with neurological involvement; patients with a history of previous surgery at the fracture site; people with multiple injuries, people with Multiple fractures and people who do not have conscious consent.

Intervention groups

Patients who have undergone sterile surgery and for whom a plaque is fixed; The next group of patients who are followed up using functional braces.

Main outcome variables

According to the results of this trial, we have achieved a preferred method that can optimize the treatment method, treatment cost, duration and quality of treatment for us.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052152N1**

Registration date: **2021-09-30, 1400/07/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-30, 1400/07/08**

Update count: **0**

Registration date

2021-09-30, 1400/07/08

Registrant information

Name

Ali Bahador

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3321 1291

Email address

aliba1392@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two methods of Fixation with a Plaque and Functional brace in The treatment of Humerus trunk fracture in Patients referred to Bahonar Hospital

Public title
Comparison of "Humerus fusion, in surgical methods with non-surgical methods"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Includes people 18 to 60 years old who are adults
Includes people who have informed and written consent

Exclusion criteria:
Patients below 18 or over 60
Patients with open wounds at the fracture site
Patients with neurological involvement
Patients with a history of previous surgery at the same fracture site
Patients with multiple injuries and fractures
Patients who don't have informed consent

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: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Ethics committee of Kerman University of Medical Sciences

Street address
Doctor blvd. Daneshvar st.

City
Kerman
Province
Kerman
Postal code
7617735845

Approval date
2021-07-12, 1400/04/21

Ethics committee reference number
IR.KMU.REC.1400.224

Health conditions studied

1

Description of health condition studied

Humerus shaft fracture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Formation of bone callus correctly and in the required amount that does not lead to a change in the schematic of the bone, and in normal time, welding and formation of bone callus that can provide activities similar to the patient's previous activities.

Timepoint

The two groups are examined in weeks 0-2-4-12-24 and also during the visits, the patient is radiographed and examined for bone formation at the fracture site. Also, the patient is followed up by telephone for three months.

Method of measurement

Observation of bone callus at the fracture site using bone radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group is referred to the operating room and after the initial procedures, it is operated by sterile method and fixation with plaque is performed for them.

Category

Treatment - Surgery

2

Description

Intervention group: The second intervention group is followed by uslap in the emergency room and after one day They are discharged with functional Sarminto braces

Category

Treatment - Surgery

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Ali Bahador

Street address

Qaraney st.

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7613747181

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bahonarhospitalresearch@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ali Bahador

Street address

The beginning of Haft Bagh Blvd. Campus of
University of Medical Sciences

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7616913555

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international@kmu.ac.ir

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

Ali Bahador

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Fax**Email**

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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 data received from the subjects after the unidentifiable individuals can be shared, including the type of fracture, the location of the fracture, the type of intervention and the outcome of the intervention.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Allow access to researchers and academic centers

Under which criteria data/document could be used

Access to the data is allowed with the permission of the university for conducting clinical research and use to choose the treatment method

From where data/document is obtainable

Dr. Amir Reza Sadeghifar 09123377411 Dr. Ali Bahador 09135011190

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

After writing the required letter of data and confirmation of the school of origin and the school of destination and a copy of the letter to the mentioned people, after reviewing the information will be sent to the school of destination in a confidential letter. It should be noted that this process takes at least two months.

Comments