Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 below18 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Bahonar Hospital, Kerman

Full name of responsible person
Ali Bahador

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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The beginning of Haft Bagh Blvd. Campus of University of Medical Sciences

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7616913555

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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

Type of organization providing the funding
Academic

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
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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