

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating of therapeutic results of metacarpal fixation using pin and mini-plate procedures in patients with transverse or short oblique metacarpal fractures

Protocol summary

Study aim

The aim of the current study is to compare the result of mini plate and K-wire fixation in transverse or short oblique metacarpal fracture

Design

This study will be a clinical trial with parallel groups with randomization using a random number table with a sample size of approximately 120 people. Study groups include Miniplate and K-wire

Settings and conduct

In 2020 to 2022 in Kashani Hospital, Isfahan province. All patients who referred to this center due to transverse or oblique metacarpal fractures were included in this study and were randomly included in one of the two study groups. After the operation, the complications and results of the operation will be compared. Outcome assessors were blinded in this study.

Participants/Inclusion and exclusion criteria

The inclusion criteria for patients were age between 18-50 years, Isolated closed transverse or oblique metacarpal fractures, candidacy for surgical treatment, and informed consent to enter the study. Exclusion criteria were simultaneous fracture in the upper limb or multiple trauma, unwillingness to participate in the study, non-referral for follow-up treatment, malignancy, osteoarthritis, major systemic disease, and taking drugs that affect fracture healing, such as steroid and anticancer drugs.

Intervention groups

Mini plate and K-wire group

Main outcome variables

ROM; DASH; sf36; infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230102057026N1**

Registration date: **2023-02-12, 1401/11/23**

Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

Mohammad Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6543 5059

Email address

dr.mohammadamiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

2023-02-20, 1401/12/01

Actual recruitment end date

2023-02-20, 1401/12/01

Trial completion date

2023-05-22, 1402/03/01

Scientific title

Evaluating of therapeutic results of metacarpal fixation using pin and mini-plate procedures in patients with

transverse or short oblique metacarpal fractures

Public title
Evaluating of therapeutic results of metacarpal fixation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age between 18-50 years Isolated closed transverse or oblique metacarpal fractures candidacy for surgical treatment informed consent to enter the study
Exclusion criteria:
simultaneous fracture in the upper limb or multiple trauma unwillingness to participate in the study non-referral for follow-up treatment malignancy osteoarthritis major systemic disease taking drugs that affect fracture healing, such as steroid and anticancer drugs

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
A table of random numbers will be used for randomization, which will be placed in the first group if there is an even number and in the second group if there is an odd number.

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 isfahan University of Medical Sciences
Street address
Hezar garib
City
Isfahan
Province
Isfahan

Postal code
8144673461
Approval date
2021-11-14, 1400/08/23
Ethics committee reference number
IR.MUI.MED.REC.1400.635

Health conditions studied

1

Description of health condition studied
transverse or oblique metacarpal fracture
ICD-10 code
S62.20
ICD-10 code description
Unspecified fracture of metacarpal bone

Primary outcomes

1

Description
quality of life
Timepoint
3 and 12 months after surgery
Method of measurement
sf36 questionnaire

2

Description
disability
Timepoint
3 and 12 months after surgery
Method of measurement
DASH questionnaire

3

Description
infection
Timepoint
3 and 12 months after surgery
Method of measurement
physical examination

4

Description
range of motion
Timepoint
3 and 12 months after surgery
Method of measurement
physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will undergo metacarpal fracture surgery with the help of miniplate

Category

Treatment - Devices

2

Description

Control group: metacarpal fracture surgery using k wire

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Doctor Mehdi Teimouri

Street address

Hezar Jarib

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Province

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Postal code

8174673461

Phone

+98 31 3668 0048

Email

mehdi.teimouri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Doctor Mehdi Teimouri

Street address

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Phone

+98 31 3668 0048

Email

mehdi.teimouri@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Amiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Amiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Hezar Jarib
City
Isfahan
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

unavailability

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available