

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison between the method of using external fixator with plate in the treatment of comminuted intra-articular fractures of distal radius with the method of using plate alone

Protocol summary

Study aim

Determining the effect of using the combined method of external fixator with plate on the wrist function of patients compared to plate alone

Design

A randomized clinical trial with two intervention groups, the rand function of Excel software will be used to randomize. Blinding of the data analyst will also be done. In addition to fixation with a plate, patients who will have complementary treatment with an external fixator will be the main (first) intervention group. The secondary (second) intervention group will be the group that only receive the plates.

Settings and conduct

Patients referred to the emergency department in Shahid Madani Karaj Center after taking the history and examination and performing the necessary radiographs, if they meet the necessary criteria to enter the study, they will be randomized and treated, then radiologically and clinically in Regular follow-ups in the clinic (first week, third week, and then in 6 weeks, 6 months, and 9 months) are examined. Blinding of the data analyst will also be done. Blinding of the data analyst will also be done.

Participants/Inclusion and exclusion criteria

Patients between 18 and 60 years old with a fracture of the distal radius

Intervention groups

Intervention group 1: Only plate placement is done.
Intervention group 2: In addition to the plate, an external fixator is also used.

Main outcome variables

Wrist function intensity of pain radius height Non-union
Pin track infection surgical site infection CRPS Age sex
BMI Palmar tilt

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230811059117N1**

Registration date: **2023-08-27, 1402/06/05**

Registration timing: **prospective**

Last update: **2023-08-27, 1402/06/05**

Update count: **0**

Registration date

2023-08-27, 1402/06/05

Registrant information

Name

Milad Behzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2266 3267

Email address

drmiladbehzadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the method of using external fixator with plate in the treatment of comminuted intra-articular fractures of distal radius with the method of using plate alone

Public title

Evaluation of the effect of using external fixator in conjunction of plate in wrist fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

acute intra articular and comminuted fractures of distal radius (AO type c2,c3) age between 18-60 years old

Exclusion criteria:

pathologic fractures early osteoporosis alcohol and drug abuse open fracture (gustilo-anderson type 2 and 3) associated fracture (except for ulnar styloid) patients with probability of poor compliance

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

For sampling, the block randomization method will be used. Thus, initially in the Excel software, blocks as (AA, BB), (BB, AA), (AB, BA), (BA, AB), (AB, AB), (BA, BA) will be prepared. A will be for the treatment or intervention group and B will be for the comparison group. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the block, people will be selected. Eligible persons will be assigned to treatment or comparison groups. This random process of selecting blocks and assigning people to intervention and comparison groups will continue until reaching the desired sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst will be blinded so that the analyst does not know which of the study groups the patients belong to.

Placebo

Not used

Assignment

Parallel

Other design features

In the control group, only plaque placement is done, and in the intervention group, in addition to the plaque, an external fixator is also used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Jahanshahr, Madani square, Shahid Madani hospital

City

Karaj

Province

Alborz

Postal code

3143744693

Approval date

2023-07-26, 1402/05/04

Ethics committee reference number

IR.ABZUMS.REC.1402.112

Health conditions studied

1

Description of health condition studied

Distal radius fracture

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

function of wrist

Timepoint

9 months after surgery

Method of measurement

QuickDASH questionnaire

2

Description

intensity of pain

Timepoint

9 months after surgery

Method of measurement

VAS Score

Secondary outcomes

1

Description

pin tract infection

Timepoint

The first, third and sixth week after surgery in the clinic

Method of measurement

Physical examination

2

Description

surgical site infection

Timepoint

The first, third and sixth week and the sixth and ninth month after surgery in the clinic

Method of measurement

Physical examination

3

Description

CRPS

Timepoint

The first, third and sixth week and the sixth and ninth month after surgery in the clinic

Method of measurement

Physical examination

4

Description

radial height, palmar tilt

Timepoint

First, third, sixth week and ninth month after surgery

Method of measurement

radiography

5

Description

non union

Timepoint

sixth month

Method of measurement

radiography

Intervention groups

1

Description

Intervention group: Use of combined external fixator in addition to plate

Category

Treatment - Surgery

2

Description

Control group: use of plate alone

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital of Karaj

Full name of responsible person

Arvin Najafi

Street address

Jahanshahr, shahid Madani hospital

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

Info@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

Street address

Jahanshahr, shahid Madani hospital

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

info@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Milad Behzadi

Position

Orthopedic specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Intersection of Hashemi Rafsanjani and Valiasr
Highways, Shahid Rajaei Hospital, Bo Ali Building, Unit
302

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 2266 3267

Email

Drmiladbehzadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Milad Behzadi

Position

Orthopedic assistant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Jahanshahr, Shahid madani hospital

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 21 2266 3267

Fax**Email**

drmiladbehzadi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Milad Behzadi

Position

Orthopedic specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Intersection of Hashemi Rafsanjani and Valiasr
Highways, Shahid Rajaei Hospital, Bo Ali Building, Unit
302

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 2266 3267

Email

Drmiladbehzadi@gmail.com

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

There is no further information

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

results of patients data analysis

When the data will become available and for how long

2024 summer

To whom data/document is available

for all

Under which criteria data/document could be used

none

From where data/document is obtainable

drmiladbehzadi@gmail.com

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

send an email it will take almost two weeks

Comments