Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 osteoprosis 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
Orthopeadic assistant

Latest degree
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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

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Karaj University of Medical Sciences

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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