

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between “External Fixation” and “Percutaneous Pinning” in the Treatment of Distal Radius Fractures and Investigation of their Skin Complications: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison between "percutaneous pinning" and "external fixation" in distal radius fractures (DRF) and investigation of their skin complications, in the intervals of 2 weeks, 6 weeks, 3 months and 6 months after surgery.

Design

Randomized clinical trial, two parallel groups of 64 patients, without blinding, using blocked randomization

Settings and conduct

Surgeries will done by orthopedic surgeons in Bohlool hospital (Gonabad, Razavi-Khorasan, Iran). Methods of surgeries noted in "Intervention" section.

Participants/Inclusion and exclusion criteria

Patients with closed and extra-articular DRF between 18 and 65 years old

Intervention groups

1. Percutaneous pinning group: we will use two or three wires to fix the fracture. One in the styloid process of radius and the other in the ulnar side of radius. 2. External fixation group: in this method we will put two schanz pins in 2nd metacarpal bone and two in radius; Then we will bridge the radiocarpal joint using external fixator.

Main outcome variables

The following variables will be evaluated in each group: Wrist range of motion; Damage or rupture of the extensor pollicis longus tendon; Neuropathy; Pin site infection; Complex regional pain syndrome (CRPS); Contact dermatitis (irritant or allergic) in the presence of pins and casts; Hypertrichosis; Quantitative assessment of response to treatment and patient function (using Mayo score); Degree of wrist disability (using DASH score); and Radiological variables such as, volar angle, ulnar variance, radial shortening and radial deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211107052989N1**

Registration date: **2021-11-25, 1400/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

Registration date

2021-11-25, 1400/09/04

Registrant information

Name

Mehran Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3967

Email address

khazaei.m.stu@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between “External Fixation” and “Percutaneous Pinning” in the Treatment of Distal Radius Fractures and Investigation of their Skin Complications: A Randomized Clinical Trial

Public title

Comparison between Surgical Treatments of Distal Radius Fracture and Investigation of their Skin Complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Closed Distal Radius Fracture Extra-articular Distal Radius Fracture

Exclusion criteria:

Unstable Distal Radius Fracture Multiple Fractures Previous Distal Radius Fracture Peripheral Neuropathy Rheumatoid Arthritis Metabolic bone diseases (e.g. Osteomalacia, Osteoporosis) Diabetes

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use "Block randomization" in this study. The size of all blocks will be equal; As a result, in this two-group study, there will be quadruple blocks (including two cases from the External Fixation group and two cases from the Percutaneous Pinning group) and there will be six acceptable sequences: AABB, ABAB, ABBA, BAAB, BABA, BBAA. In the next step, we randomly will choose from the acceptable sequences, so that we can have our required sample size (for example, to have 64 cases, we will need 16 quadruple sequences). Each random sequence will be recorded on a card and the cards will be enveloped and placed inside a box. For each participant, one of the envelopes will be opened and the assigned group of that participant will be revealed.

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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan-Razavi, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.GMU.REC.1400.090

Health conditions studied

1

Description of health condition studied

Distal Radius Fracture (DRF)

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

Wrist range of motion

Timepoint

6 weeks, 3 months, 6 months after surgery

Method of measurement

goniometer

2

Description

damage or rupture of extensor pollicis longus tendon

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

physical examination

3

Description

radial or median nerve neuropathy

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

physical examination

4

Description

pin site infection

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

DAHL classification of pin site infection

5

Description

complex regional pain syndrome

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

physical examination

6

Description

Irritant or allergic contact dermatitis in the presence of pins and casts

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

physical examination

7

Description

Hypertrichosis

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

physical examination

8

Description

quantitative assessment of response to treatment and patient function

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

Mayo score

9

Description

severity of disability

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

The Disabilities of the Arm, Shoulder and Hand (DASH) Score

10

Description

volar tilt

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

wrist anteroposterior (AP) and lateral view x-ray

11

Description

ulnar (Hulten) variance

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

wrist anteroposterior (AP) and lateral view x-ray

12

Description

radial shortening

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

wrist anteroposterior (AP) and lateral view x-ray

13

Description

Radial deviation

Timepoint

2 weeks, 6 weeks, 3 months, 6 months after surgery

Method of measurement

wrist anteroposterior (AP) and lateral view x-ray

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Percutaneous pinning: we will use two or three wires to fix the fracture. One in the styloid process of radius and the other in the ulnar side of radius.

Category

Treatment - Surgery

2

Description

Intervention group: External fixation: in this method we will put two schanz pins in 2nd metacarpal bone and two in radius; Then we will bridge the radiocarpal joint using external fixator.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul hospital

Full name of responsible person

Meisam Moradi

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Parastar Blvd., Sa'adi Ave., Bohlool hospital

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mehran Khazaei

Position

Medical 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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Meisam Moradi

Position

Consultant

Latest degree

Specialist

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

1. Deidentified Individual Participant Data Set (IPD): Once unidentificaton, all potential data will be available.
2. Study Protocol: Will be completely available.
3. Statistical Analysis Plan: Includes the way in which the data will be statistically evaluated.
4. Informed Consent Form: The unfilled form of informed consent will be available. The form of each patient will not be available due to ethics.
5. Clinical Study Report: Will be completely available.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

It is only available for people working in academic institutions or people working in related businesses (e.g., biomedical engineering).

Under which criteria data/document could be used

Access to data will be available for mentioned groups and individuals, if the request contains: "what are required, the reason of requirement, and the type of analysis to be performed on the data". Reasons of requirement include: writing meta-analyzes or review articles, evaluating confounders and conducting complementary projects, and using data for engineering sciences research projects.

From where data/document is obtainable

People can contact any of the following to request. The request should include "what are required, the reason of requirement, and the type of analysis to be performed on the data". Mehran Khazaei Phone No.: 00989105620084 E-mail: Mehran_Khazaei@yahoo.com

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

A. Sending request by applicant B. Receiving the request and reviewing by of the project C. Documenting the requested data in the appropriate format D. Sending data to the applicant * The total time required for this process will be 3-6 working days, depending on the volume of requested information and their format. ** This time may last longer for "Statistical Analysis Plan" (up to two weeks)

Comments