

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of manual reduction vs. new tractional technique in distal radius fractures

Protocol summary

Study aim

Comparison of manual reduction method and modern stretching method in the success rate of distal radius fracture reduction and its outcome

Design

In this clinical trial (without blindness), 30 patients with distal radius fractures, using the Excel Rand function will be randomly assigned to two parallel groups of 15 people. The first group will be performed by traditional method, reduction by hand and the second group by new method under fluoroscopic instruments.

Settings and conduct

This study will be performed on patients with distal radius fractures referred to the orthopedic clinic of Besat hospital in Hamadan. In order to repair the fracture, two traditional methods and the new method will be used. In both groups, after fracture reduction, casting is performed and then patients, one week and five weeks after treatment, will be referred to clinic for care and evaluation of treatment outcome.

Participants/Inclusion and exclusion criteria

Participants included patients over 16 years of age with distal radius fractures who consented to participate in the study. Patients with joint involvement, open fractures and soft tissue damage will not be eligible for the study.

Intervention groups

The first group of distal radius fractures, in the traditional way, will be subjected to manual reduction. In this method, the physician's assistant pulls the wrist with great force and then bends it at an angle of 15 degrees. The surgeon simultaneously repairs the fracture. In the new method, using the patient's elbows and fingers, it is hung from the bed and attached to the weight. Then, under fluoroscopy, the surgeon places the injured part in the proper direction.

Main outcome variables

The main consequence of improving the distal radius fracture, improving hand function, reducing pain at the fracture site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N21**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of manual reduction vs. new tractional technique in distal radius fractures

Public title

Reduction of the distal radius fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Radial radius fracture Age over 16 years Posterior rotation less than 15 degrees and radius shortening less than 5 mm

Exclusion criteria:

Joint involvement Open fractures and soft tissue damage Severe bone damage

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

30 samples with computer software will be randomly coded in two groups I and C and the codes will be entered on the raw checklists. Upon referral of a qualified patient, one of the checklists will be randomly selected. If the selected code is I, the Fracture reduction will be with instrument and if it is C, it manual Fracture reduction will be done.

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 Hamadan University of Medical Science

Street address

Şahid Fahmideh Ave

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Postal code

6517838697

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.UMSHA.REC.1401.032

Health conditions studied

1

Description of health condition studied

Distal radius fracture

ICD-10 code

M84.33

ICD-10 code description

Stress fracture, ulna and radius

Primary outcomes

1

Description

Radius fracture reduction

Timepoint

First and five week after treatment

Method of measurement

Radiography

2

Description

Radial size

Timepoint

First and five week after treatment

Method of measurement

Radiography

3

Description

Radial deformation

Timepoint

First and five week after treatment

Method of measurement

Radiography

Secondary outcomes

1

Description

Postoperative patients' pain score

Timepoint

Fifth week of treatment

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: In this group, the traditional method based on pressure and traction by surgeons hand Fracture reduction will be performed

Category

Treatment - Surgery

2

Description

Control group: In this group, using a new method, mechanical tools will be used to create pressure and traction fracture reduction.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Erfan Rohani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

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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

No more information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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