

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of applying distortion force on distal radial fractures parallel to radius shaft and perpendicular to joint in radiology and clinic

Protocol summary

Study aim

Effect of distraction force as parallel to radius shaft or perpendicular to distal radius joint line on radiographic reduction of distal radius fracture and clinical results

Design

Two arm intervention parallel group, not blinded, randomized trial with sealed envelopes randomization and 6-week follow-up for postoperative radiologic and clinical results

Settings and conduct

This trial would be done in Shahid Kamyab and Imam Reza Hospitals of Mashhad University of Medical Sciences. Patients are included after informed consent obtained and they allocate to either of intervention groups according to sealed envelopes randomization method. Clinical indices include wrist function and pain and radiologic indices were assessed in follow-up, 6 weeks after the operation.

Participants/Inclusion and exclusion criteria

patients in 18 to 60 years with unilateral acute distal radius fracture with more than 5 millimeters shortening without previous fracture, open fracture or inflammatory disease

Intervention groups

First intervention group: applying distraction force as parallel to radius shaft using pre-fabricated Avisa external fixator Second intervention group: applying distraction force as perpendicular to distal radius joint line using pre-fabricated Avisa external fixator

Main outcome variables

Radiologic indices; Clinical indices include wrist function and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200313046759N1**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **retrospective**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Davood Jafari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of applying distortion force on distal radial fractures parallel to radius shaft and

perpendicular to joint in radiology and clinic

Public title

Effect of applying distortion force on distal radial fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute unilateral distal radial fracture with above 5 millimeter shortening or intra-articular

Exclusion criteria:

bilateral fracture Inflammatory disease of involved side open fracture History of any previous fracture in either right or left wrist

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization is simple. Unit of randomization is individual. Randomization tool is sealed envelopes. For each patient with inclusion criteria, a sealed envelope is taken and patient's group determined accordingly. As using wrist external fixator, allocation concealment is impossible for neither the patient nor the surgeon.

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 Mashhad University of Medical Sciences

Street address

Orthopedics research center, Quaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.697

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

Palmar tilt

Timepoint

6 weeks after the surgery

Method of measurement

in degrees in 6 weeks post-op lateral wrist radiography

2

Description

radial inclination

Timepoint

6 weeks after the surgery

Method of measurement

in degrees in 6 weeks post-op anteroposterior wrist radiography

Secondary outcomes

1

Description

pain

Timepoint

before surgery, immediately after the surgery, 6 weeks after the surgery

Method of measurement

Visual analogue scale

2

Description

wrist function

Timepoint

6 weeks after the surgery

Method of measurement

Modified Mayo wrist score

3

Description

wrist function

Timepoint

6 weeks after the surgery

Method of measurement

Patient-Rated Wrist Evaluation questionnaire

4

Description

wrist function

Timepoint

6 weeks after the surgery

Method of measurement

Quick Disabilities of the Arm, Shoulder and Hand questionnaire

Intervention groups

1

Description

Intervention group 1: In sterile condition of operating room under general anesthesia and prep and drape, first closed reduction with appropriate maneuver is done. Then 2 two millimeters schanz pins in second metacarpus and 2 two millimeters schanz pins in radius shaft is inserted in lateral side. Then Aviso Co. wrist external fixator is attached to these schanz pins. We put radial inclination and palmar tilt indices to zero value and distraction force is applied in parallel to radius shaft. All procedures were checked by fluoroscopy.

Category

Treatment - Surgery

2

Description

Intervention group 2: In sterile condition of operating room under general anesthesia and prep and drape, first closed reduction with appropriate maneuver is done. Then 2 two millimeters schanz pins in second metacarpus and 2 two millimeters schanz pins in radius shaft is inserted in lateral side. Then Aviso Co. wrist external fixator is attached to these schanz pins. We put radial inclination and palmar tilt indices as the other side values and distraction force is applied perpendicular to distal radius joint line. All procedures were checked by fluoroscopy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ali Khorsand

Street address

Imam Reza Hospital, Imam Reza Sq., Ebn Sina St.

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2

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital

Full name of responsible person

Alireza Mahmoudi Gharaei

Street address

Shahid Kamyab Hospital, Fadaeian Islam St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice research department, Qureshi Building, Daneshgah St.

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Ali Moradi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Ali Moradi

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Latest degree

Subspecialist

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Potentially all collected deidentified IPD could be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Potentially, academic use of all data is possible

From where data/document is obtainable

Please contact with below email in order to request data:

Moradial@mums.ac.ir

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

2 working weeks after receiving request email

Comments