Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 envelops 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 envelops 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

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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 envelops. 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 Avisa 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 Avisa 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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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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