

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Surgical versus conservative management of distal radius fracture with coronal shift (18 to 55 old); a randomized controlled trial for the first time

Protocol summary

Study aim

The comparison of function, range of motion, and pain intensity in the two-year follow-up of patients with distal radius fracture with coronal shift undergoing surgical management versus conservative management

Design

Randomized control trial , parallel and RAND function in 50 patient.

Settings and conduct

50 patients with distal radial fracture referred to the Kashani Hospital affiliated at Isfahan University of Medical Sciences from March 2014 to April 2017. Randomized with excell software in two groups surgery with plate and close reduction and casting. without blindness

Participants/Inclusion and exclusion criteria

distal radius fracture with coronal shift in 18 to 55 without previous wrist surgery

Intervention groups

"Intervention group": Surgery and fixation with plate.
"Control group": Close reduction and Casting

Main outcome variables

functional score on the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire; pain score based on Visual Analogue Scale (VAS), and handgrip strength (HGS) measured via a dynamometer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200604047653N1**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **retrospective**

Last update: **2020-09-07, 1399/06/17**

Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

Meghdad Rahmani Doulatabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-01, 1395/12/11

Expected recruitment end date

2019-04-01, 1398/01/12

Actual recruitment start date

2017-03-01, 1395/12/11

Actual recruitment end date

2019-04-01, 1398/01/12

Trial completion date

2019-04-01, 1398/01/12

Scientific title

Surgical versus conservative management of distal radius fracture with coronal shift (18 to 55 old); a randomized controlled trial for the first time

Public title

Surgical versus conservative management of distal radius fracture with coronal shift; a randomized controlled trial for the first time

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Distal radius fracture type 1 Fernandez with coronal shift

Exclusion criteria:

previous surgery in wrist

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Isfahan university of medical science

Street address

Isfahan University of Medical Science, Hezar Jarib Ave, Isfahan

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Postal code

8177787755

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.MUI.MED.REC.1398.054

Health conditions studied

1

Description of health condition studied

Distal radius fracture type 1 Fernandez with coronal shift

ICD-10 code

S52.50

ICD-10 code description

Unspecified fracture of the lower end of radius

Primary outcomes

1

Description

function scoring DASH,

Timepoint

24 month after treatment

Method of measurement

Clinical evaluation and dynamometer

2

Description

pain scoring VAS,

Timepoint

24 month after treatment

Method of measurement

Clinical evaluation and dynamometer

3

Description

handgrip strength scorin HGS

Timepoint

24 month after treatment

Method of measurement

Clinical evaluation and dynamometer

Secondary outcomes

1

Description

-pain score based on Visual Analogue Scale (VAS) after 24 month

Timepoint

handgrip strength (HGS) measured via a dynamometer 24 month after treatment

Method of measurement

Medical Dynamometer

Intervention groups

1

Description

"Control group": Close reduction and Casting.

Category

Treatment - Surgery

2

Description

Intervention group: Open reduction and instrumentation

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital in Isfahan

Full name of responsible person

Meghdad Rahmani

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Kashani Hospital, Kashani Ave, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Proportion provided by this source

20

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

Esfahan University of Medical Sciences

Full name of responsible person

Meghdad Rahmani

Position

Orthopedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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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

No - There is not a plan to make this available

Analytic Code

No - There is not 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

data sets are to be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

open access

From where data/document is obtainable

use Email

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

will be send via Email

Comments