

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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)

###### Phone

+98 31 3779 0201

###### Email address

meghdad\_rahmani@yahoo.com

##### 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

**City**

Isfahan

**Province**

Isfahan

**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

**Street address**

Kashani Hospital, Kashani Ave, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8177787755

**Phone**

+98 31 3235 0004

**Email**

Meghdad\_rahmani@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaqayeq Haghjoojavanmard

**Street address**

Isfahan university of medical science, hezar jarib ave, isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8177787755

**Phone**

+98 31 3779 0201

**Email**

Meghdad\_rahmani@yahoo.com

**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

**Street address**

Orthopedic department, Alzahra Hospital, Sofe Street, Isfahan, Iran

**City**

Tehran

**Province**

Isfahan

**Postal code**

12345

**Phone**

+98 912 326 9727

**Email**

meghdad\_rahmani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Meghdad Rahmani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Orthopedic Department, Alzahra Hospital, Sofe Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

0316685555

**Email**

meghdad\_rahmani@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Meghdad Rahmani Doulatatabadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Orthopedic department, Alzahra Hospital, Sofe Street,  
Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3779 0201

**Email**

Meghdad\_rahmani@yahoo.com

**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**