Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Isfehan

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 Dynanometer

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
Isfehan
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
Isfehan
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
Isfehan
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 Depatrment, Alzahra Hospital, Sofe Street
City
Isfahan
Province
Isfehan
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 Doulatabadi
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

Isfehan

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