

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial study of the assessment of the effect of a long arm cast with Thumb Spica arm cast in the treatment of patients with distal radius fractures without displacement

Protocol summary

Study aim

1- Comparison of the effects of long arm cast and Thumb Spica arm cast on hand reduction 2- Comparison of the effect of long arm cast and Thumb Spica arm cast on the range of motion of the wrist joint.

Design

Clinical trials with a hospital-based and pragmatic control group with parallel, randomized groups, Group 1: Treatment with the long arm cast, Group 2: Treatment with the Thumb Spica arm cast, randomization method Simple randomization, randomization unit: Individual, randomization tool: Random number table, no blinded, The total sample size of 80 patients with distal radius fractures without displacement in 2 groups, clinical trial phase: 3.

Settings and conduct

Distal radius fracture is among the most common fractures of the long bones that are seen in all age groups. Treatment of these fractures in simple cases with displacement or intraarticular fractures inaction, and if the fracture has dislocation may be required surgery. The aim of the study is a comparison of treatment effect in the methods of a long cast and Thumb Spica Cast in the patients with distal radius fractures without displacement. Patients referred to the Baqiyatallah hospital who was diagnosed with distal radius fractures without displacement. Group 1: Treatment with the long arm cast, Group 2: Treatment with the Thumb Spica arm cast, randomization method Simple randomization, randomization tool: Random number table, The total sample size of 80 patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with distal radius fractures without displacement, Exclusion criteria: Patients with Intraarterial fractures of Distal Radius, fracture greater than 20 degrees of dorsal angulation.

Intervention groups

Group 1: Treatment with the long arm cast. Group 2: Treatment with the Thumb Spica arm cast.

Main outcome variables

Hand reduction, The range of motion of the wrist joint.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042524N1**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

Registration date

2019-03-17, 1397/12/26

Registrant information

Name

Hamid Reza Rasouli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8805 3766

Email address

rsr.rasouli@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-09-16, 1397/06/25

Actual recruitment start date

2017-05-22, 1396/03/01
Actual recruitment end date
2018-10-12, 1397/07/20
Trial completion date
2018-11-03, 1397/08/12

Scientific title
Clinical trial study of the assessment of the effect of a long arm cast with Thumb Spica arm cast in the treatment of patients with distal radius fractures without displacement

Public title
The assessment of the effect of a long arm cast with Thumb Spica arm cast in the treatment of patients with distal radius fractures without displacement

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with distal radius fractures without displacement
Exclusion criteria:
Patients with Intraarterial fractures of Distal Radius
Patients with fracture greater than 20 degrees of dorsal angulation

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table

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 Baqiyatallah University of

Medical Sciences
Street address
Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran
City
Tehran
Province
Tehran
Postal code
1435917541
Approval date
2017-05-02, 1396/02/12
Ethics committee reference number
IRB.BMSU.RC.1396.344

Health conditions studied

1

Description of health condition studied

Distal radius fractures without displacement

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

Hand reduction

Timepoint

Six weeks after treatment

Method of measurement

DASH questionnaire

2

Description

The range of motion of the wrist joint

Timepoint

Six weeks after treatment

Method of measurement

DASH questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Thumb Spica arm cast for 6 weeks, Spica cast is not gypsum but a kind of casting. Thumb Spica arm cast at the radial surface of the forearm is placed in order to immobilize the thumb and prevent the flexion and extension of the wrist. This splint extends from the tip of the thumb to the proximal forearm. Place the forearm in a neutral position, while the wrist has a

20-degree extension and the shoulder is bent slightly.

Category

Treatment - Devices

2

Description

Control group: Long arm cast for 6 weeks, long arm cast is a cast of the forearm in order to relieve articulation and joint wrists in the distal radius fracture.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Baqiyatallah hospital

Full name of responsible person

Sadrollah Mahmoudi

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee St, Tehran

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droserik@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamid Reza Rasouli

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran

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pajuhesh_trauma@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Sadrollah Mahmoudi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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

Print article

When the data will become available and for how long

8 months

To whom data/document is available

Medical students

Under which criteria data/document could be used

Print article

From where data/document is obtainable

Sadrollah Mahmoudi

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

Question

Comments

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Sadrollah Mahmoudi

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