

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of continuous passive motion device on pain, range of motion and function in patients with distal radius fractures

#### Protocol summary

##### Study aim

This is a clinical trial study to improve the therapeutic methods and shorten the duration of treatment in patients with distal radius fracture and determine the effectiveness of using the Continuous Passive Motion (CPM) machine on pain, range of motion and function.

##### Design

In this double blind study, 22 patients with a diagnosis of distal radius fractures and entry conditions who are referred to a study referring to the Rehabilitation Center Asma. Participants are randomly divided into intervention and control groups And undergo standard rehab in four weeks.

##### Settings and conduct

The statistical population in this study is 22 patients over 18 years of age in Tehran with a distal radius fracture that after retrieving the fixator for rehabilitation. Sampling will be done in an accessible manner, then randomly, patients will be divided into two groups of standard treatments using CPM (intervention) and standard (control) treatments with a sample size of 11 people per group. During 12 sessions (4 weeks) they will undergo standard rehab and will be re-evaluated at weeks 4.6 and 12 after rehab.

##### Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study include people over the age of 18 who have a distal radius fracture and who has come to rehab after removing the fixation

##### Intervention groups

Intervention group: A group that also uses CPM devices in addition to receiving common therapeutic exercises .  
Control group: A group that only receives common therapeutic exercises.

##### Main outcome variables

Reduce pain, increase the range of motion, improve function

#### General information

##### Reason for update

##### Acronym

CPMDRFx

##### IRCT registration information

IRCT registration number: **IRCT20180531039924N1**

Registration date: **2018-06-15, 1397/03/25**

Registration timing: **prospective**

Last update: **2018-06-15, 1397/03/25**

Update count: **0**

##### Registration date

2018-06-15, 1397/03/25

##### Registrant information

##### Name

Arezo Shizadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0037

##### Email address

Ar.Shirzadi@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-23, 1397/04/02

##### Expected recruitment end date

2018-10-22, 1397/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of continuous passive motion device on pain, range of motion and function in patients with distal radius fractures

## Public title

Effect of Continuous Passive Motion (CPM) on distal radius fractures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients over the age of 18 with radial distal fractures referring to rehabilitation after removing the fixation

### Exclusion criteria:

Having a history of fracture in the affected wrist, which reduces the range of motion or function

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **22**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization will be done with sealed envelopes. Allocation will be concealed and Patients will be include in one of the two intervention or control groups and receive intervention from their own group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

participants and the assessors will be blind , but therapist cant be masked

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

##### Street address

Daneshjoo Blvd, Evin, Tehran,I ran

##### City

Tehran

## Province

Tehran

## Postal code

1985713834

## Approval date

2018-02-26, 1396/12/07

## Ethics committee reference number

IR.USWR.REC.1396.295

## 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

pain

#### Timepoint

The beginning of treatment, the fourth week, the sixth and the twelfth weeks

#### Method of measurement

Visual Analog Scale(VAS)

## Secondary outcomes

### 1

#### Description

Rang Of Motion (ROM)

#### Timepoint

The beginning of treatment, the fourth week, the sixth and the twelfth weeks

#### Method of measurement

Goniometer

### 2

#### Description

Function

#### Timepoint

The beginning of treatment, the fourth week, the sixth and the twelfth weeks

#### Method of measurement

The Patient-Rated Wrist Hand Evaluation(PRWHE)

## Intervention groups

### 1

#### Description

Control group: conservative treatment

**Category**

Rehabilitation

**2****Description**

Intervention group: conservative treatment and CPM device

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Asma rehabilitation center

**Full name of responsible person**

Maryam Farzad

**Street address**

Corner of Twelve St, Asad Abadi Street, Yousef Abad

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Department of Occupational Therapy

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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**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Arezoo Shirzadi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

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**Position**

PHD of Occupational Therapy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Arezoo Shirzadi

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Master student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available