

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Arezoo Shirzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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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

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Postal code

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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

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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

Arezo Shirzadi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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