

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of early versus late exercise initiation on the incidence of complex regional pain syndrome in patients with distal radius fractures

Protocol summary

Study aim

Comparison of the effect of early versus late exercise initiation on the incidence of complex regional pain syndrome in patients with distal radius fractures

Design

A randomized, single-blind, parallel-group, controlled phase 2-3 clinical trial will be conducted on 192 patients. Randomization will be performed using the RAND function in Microsoft Excel.

Settings and conduct

This randomized clinical trial is conducted at Rasoul Akram Hospital in Tehran. Patients aged 18-70 years with distal radius fractures are included. Patients are allocated to intervention and control groups using block randomization via Excel. The intervention group starts exercise the day after surgery or cast removal, and the control group starts at the time determined by the physician. Blinding is assessor-blind (single-blind). Outcomes are assessed at weeks 1, 2, and 6 using the Budapest criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of distal radius fracture based on clinical and radiographic evidence, age range 18-70 years, patients with multiple trauma accompanied by distal radius fracture. Exclusion criteria: History of wrist fracture, central nervous system injury, spinal cord lesion, known neuropathy, burn, muscle atrophy, pathological wrist fracture, wrist injury with fracture other than distal radius, unwillingness to participate in the study.

Intervention groups

Intervention group (early exercise initiation): Patients in this group will perform exercises including 4 types of hand, wrist, and finger movements, each 5 times during waking hours, starting from the day after surgery or the day after cast removal, pin removal, or external fixator removal. Control group (late exercise initiation): Patients

in this group will perform the same exercises later, at the time determined by the physician

Main outcome variables

complex regional pain syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260825070794N1**

Registration date: **2026-08-27, 1405/06/05**

Registration timing: **prospective**

Last update: **2026-08-27, 1405/06/05**

Update count: **0**

Registration date

2026-08-27, 1405/06/05

Registrant information

Name

Esmaeil Fathollahierami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86709

Email address

e.fathollahierami@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-10-12, 1405/07/20

Expected recruitment end date

2027-10-22, 1406/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of early versus late exercise initiation on the incidence of complex regional pain syndrome in patients with distal radius fractures

Public title
The effect of early versus late exercise initiation on the incidence of complex regional pain syndrome in patients with wrist fractures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of distal radius fracture based on clinical and radiographic evidence Age range 18-70 years Patients with multiple trauma accompanied by distal radius fracture
Exclusion criteria:
 History of wrist fracture History of wrist fracture Spinal cord lesion Known neuropathy Burn Muscle atrophy Pathological wrist fracture Wrist injury with fracture other than distal radius Unwillingness to participate in the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study will be performed using block randomization with quadruple blocks, and the unit of randomization is individual. The randomization sequence will be generated using Microsoft Excel and the RAND function, and after determining the patient's treatment type, the software generates a block randomization sequence and assigns the patient to either the intervention or control group. To conceal the allocation sequence, sealed, opaque, and sequentially numbered envelopes will be used, each containing a group code, and until the envelope is opened, neither the research team nor the patient will be aware of the group assignment. The envelopes will be prepared and numbered by an individual independent of the research team, and patients, in order of referral, will open their respective envelope and be assigned to one of the two groups based on the code inside.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding in this study is performed as assessor-blind, meaning that only the outcome assessor remains blinded to the study group allocation. For blinding of the outcome assessor, the examining physician who evaluates the primary outcome is unaware of the patients' group allocation and records clinical information without knowledge of the intervention type. Patients' records are provided to them without any indication of group allocation. The exercise training researcher, although aware of the group allocation, has no role in outcome assessment and does not share the group allocation information with the outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Iran University of Medical Sciences
Street address
 Shahid Hemmat Highway, Next to Milad Tower, Tehran,
City
 Tehran
Province
 Tehran
Postal code
 1449614535
Approval date
 2026-05-21, 1405/02/31
Ethics committee reference number
 IR.IUMS.FMD.REC.1405.138

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
 Incidence of complex regional pain syndrome

Timepoint

Weeks 1, 2, and 6 after treatment

Method of measurement

In-person examination by the outcome assessor physician based on Budapest criteria (including four categories: sensory, vasomotor, sudomotor/edema, and motor/trophism)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the intervention group receive educational content including 4 types of hand, wrist, and finger movements along with instructions on how to perform them and the number of repetitions (each 5 times during waking hours) through educational videos, booklets, or training sheets, and start exercise from the day after surgery or the day after cast removal, pin removal, or external fixator removal. These patients are taught to perform each of the movements 5 times daily while awake. Weekly telephone calls will be made to this group for follow-up and to remind them to perform the exercises.

Category

Behavior

2**Description**

Control group: Patients in the control group perform the same exercises (including 4 types of hand, wrist, and finger movements) later, at the time determined by the physician. These patients also receive educational content regarding how to perform the movements and the number of repetitions (each 5 times during waking hours), but the timing of exercise initiation is delayed and determined based on the physician's judgment. Weekly telephone calls will also be made to this group for follow-up and to remind them to perform the exercises.

Category

Behavior

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

Hazrat Rasoul Akram Hospital

Full name of responsible person

Esmail Fathollahi Erami

Street address

Hazrat Rasoul Akram Hospital, Niyayesh St., Sattarkhan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

e.fathollahierami@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Majid Safa

Street address

Iran University of Medical Sciences, Central Headquarters, 5th Floor, Hemmat Expressway, next to Milad Tower, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

safa.m@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Esmail Fathollahi Erami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Hazrat Rasoul Akram Hospital, Niyayesh St.,
Sattarkhan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

e.fathollahierami@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Esmaeil Fathollahi Erami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Hazrat Rasoul Akram Hospital, Niyayesh St.,
Sattarkhan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

e.fathollahierami@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Esmaeil Fathollahi Erami

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

Hazrat Rasoul Akram Hospital, Niyayesh St.,
Sattarkhan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

e.fathollahierami@gmail.com

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