Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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
Esmaeil 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
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 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

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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

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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