

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of a course of rehabilitation exercises combined with blood flow restriction on pain, function, and muscle electrical activity in patients with patellofemoral pain syndrome.

Protocol summary

Pain, function, electrical activity of muscles

Study aim

Investigating the effect of a course of rehabilitation exercises with blood flow restriction on pain, function and electrical activity of muscles in patients with patellofemoral pain syndrome Investigating the effect of a course of rehabilitation exercises with blood flow restriction on pain in patients with patellofemoral pain syndrome Investigating the effect of a course of rehabilitation exercises with blood flow restriction on the performance of patients with patellofemoral pain syndrome Investigating the effect of a course of rehabilitation exercises with blood flow restriction on the electrical activity of muscles in patients with patellofemoral pain syndrome

Design

The clinical trial will be controlled, with parallel groups, unblinded, randomized, phase 2, and will be conducted on 30 patients.

Settings and conduct

Patients with patellofemoral pain syndrome, semi-experimental and randomized, in the laboratory of the University of Zabol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All individuals with pain in the patellofemoral joint for at least 6 weeks, exacerbation of patellofemoral joint pain in at least 2 of the following activities: squatting, kneeling, and going up and down stairs. Exclusion criteria: not participating in regular exercises, history of any surgery on the knee joint, any internal knee joint problem, presence of neurological, cardiovascular conditions related to blood, and tissue or joint injuries after performing rehabilitation exercises.

Intervention groups

1- Rehabilitation exercise group with blood flow restriction 2- Rehabilitation exercise group without blood flow restriction

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053244N2**

Registration date: **2024-12-22, 1403/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-12-22, 1403/10/02**

Update count: **0**

Registration date

2024-12-22, 1403/10/02

Registrant information

Name

Mohammadreza Rezaeipour

Name of organization / entity

University of Sistan and Baluchestan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-01-04, 1403/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of a course of rehabilitation exercises combined with blood flow restriction on pain, function, and muscle electrical activity in patients with patellofemoral pain syndrome.

Public title
Pain, function, and electrical activity of muscles

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patellofemoral pain syndrome Woman
Exclusion criteria:
Failure to provide permission to participate in sports activities

Age
From **35 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple randomization model will be used with the intervention and control groups being secretly recorded on paper and selected by the participants. In this method, the type of treatment assigned to the two groups is completely unpredictable.

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 the University of Sistan and Baluchestan

Street address

University Street

City

Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745785

Approval date

2024-11-09, 1403/08/19

Ethics committee reference number

IR.USB.REC.1403.033

Health conditions studied

1

Description of health condition studied

Patellofemoral pain syndrome

ICD-10 code

M22.2

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description

Electrical activity of muscles

Timepoint

Before starting rehabilitation exercises, 6 weeks after starting exercises

Method of measurement

Surface electromyography recording device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rehabilitation exercises with blood flow restriction: The number of people in this group is 15, the training period is 6 weeks, and they perform 3 sessions of rehabilitation exercises with blood flow restriction per week, and a cuff will be used for restriction.

Category

Rehabilitation

2

Description

Control group: Rehabilitation exercises without restricting blood flow, the number of people in this group is 15, the training duration is 6 weeks, and they perform 3 sessions of rehabilitation exercises without restricting blood flow per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Zabol

Full name of responsible person

Dr. Hadi Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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 Sistan and Baluchestan

Proportion provided by this source

20

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 Sistan and Baluchestan

Full name of responsible person

Mohammadreza Rezaeipour

Position

Associate Professor

Latest degree

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Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Requires review and obtaining necessary permissions, including from patients.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available