Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of neuromuscular training by biofeedback method and conventional exercise therapy of hip abductor muscles on pain, function and electrical activity of the muscle in patients with patellofemoral pain syndrome

Protocol summary

Study aim
Determining the effect of gluteus medius muscle training with electromyography biofeedback during Functional activities and comparing it with routine therapeutic exercise of this muscle in patients with patellofemoral pain syndrome

Design
Clinical trial with control group, with parallel groups, single-blind, randomized on 30 patients. Coin flipping is used for randomization.

Settings and conduct
The study is conducted at Shahid Beheshti University of Medical Sciences. Both groups receive the usual physiotherapy. In addition, group A receives the common exercises of the gluteus medius muscle and group B receives functional exercises along with biofeedback. The evaluator does not know the group of patients and the study is single blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18-40 years old; Anterior knee pain during at least 3 of following: stair ascent or descent, squatting, kneeling, jumping, running; Visual analog score ranging from 3 to 10; Positive patellar grind test; A history of at least 3 days of continuous pain in front of the knee (not caused by trauma) in the last 3 months, which is gradual; BMI 20-30 Exclusion criteria: Patella tendon pathology; Chondral damage of the knee joint; Osteoarthritis of the knee joint; Pain referred from the spine to the lower limbs; Neuromuscular, Rheumatology or Metabolic Diseases such as Diabetes and Neuropathy; Dislocation or subluxation of the patella and signs of meniscus or ligament damage; Trauma caused by injury or surgery in the lower limb in the last 12 months

Intervention groups
Group A receives the common strengthening exercises of the gluteus medius muscle. Group B receives functional exercises of accent and decent stairs, walking and accent and decent stairs to the side along with biofeedback

Main outcome variables
Pain intensity; Function; Onset, offset and intensity of electrical muscle activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230725058919N1**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date
2023-08-16, 1402/05/25

Registrant information

Name
Hossein Rabieifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-08-22, 1402/05/31

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of neuromuscular training by biofeedback method and conventional exercise therapy of hip abductor muscles on pain, function and electrical activity of the muscle in patients with patellofemoral pain syndrome

Public title

Comparison of neuromuscular training and conventional exercise therapy of hip abductor muscles in patients with patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-40 years old Anterior knee pain during at least 3 of the following: stair ascent or descent; squatting; kneeling; jumping; running Visual analog score ranging from 3 to 10 A history of at least 3 days of continuous pain in front of the knee (not caused by trauma) in the last 3 months, which is gradual. Not receiving medical and physical treatment in the last three months BMI 20-30 Positive patellar Grind test

Exclusion criteria:

Patella tendon pathology Chondral damage of the knee joint Osteoarthritis of the knee joint Pain referred from the spine to the lower limbs Neuromuscular, rheumatology or metabolic diseases such as diabetes and neuropathy Dislocation or subluxation of the patella and signs of meniscus or ligament damage Trauma caused by injury or surgery in the lower limb in the last 12 months

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with Non-transparent and sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B they will be tested.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the patient knows which group he is in but the evaluator dose not know so this study is one-way blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.840

Health conditions studied

1

Description of health condition studied

Anterior knee pain syndrome (patellofemoral pain syndrome)

ICD-10 code

M22.2

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)

Method of measurement

Visual Analogue Scale

2

Description
Knee function
Timepoint
Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)
Method of measurement
KOOS questionnaire

3

Description
Electromyographic activity of muscles
Timepoint
Before the start of the intervention and after the end of the 10 intervention sessions (23 days after the start of the sessions)
Method of measurement
Electromyography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Functional exercise therapy group with biofeedback: participants in 10 sessions and 3 sessions per week, in addition to regular physical therapy (the same in both groups), receive functional exercises of going up and down the stairs, walking and going up and down the stairs to the side along with biofeedback. In each of the activities, the patient is asked to increase the activity of the gluteus medius muscle, to activate the muscle early and even if possible to maintain the activity of the muscle until the end of the respective activity. The activities of going up and down the stairs and going up and down the stairs to the side are done as 4 sets with 5 repetitions and a 30-second rest between sets, and the walking activity as 4 repetitions of 90 seconds and a 30-second rest between repetitions. Each session lasts approximately 180 minutes.
Category
Rehabilitation

2

Description
Control group: Gluteus medius muscle strengthening exercise group: participants in 10 sessions and 3 sessions per week, in addition to regular physical therapy (the same in both groups), receive Gluteus medius muscle strengthening exercise group. The exercises become progressively more difficult, and when the patient can repeat the desired exercise 15 times without problems, the exercises will become more difficult and the external force will be gradually added (if 15 repetitions are done without problems, 1 pound of external resistance will be added). The exercises in order of difficulty are: abduction and external rotation in side lying position (clamshell), full thigh abduction with straight knee, thigh abduction in quadruped position. Each session lasts approximately 180 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar hospital
Full name of responsible person
Seyyed Morteza Kazemi
Street address
Akhtar Hospital., Azar Dead End., Sharifi Menesh St., in front of Qitarieh Metro., Shariati St., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hossein Rabeie Far
Position
Physiotherapy Master's student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All above will be published in the article.
When the data will become available and for how long
After the article publication
To whom data/document is available
Researchers and students in academic centers
Under which criteria data/document could be used
Other researchers and therapists in the rehabilitation and medical field can use this use the data of this study after the article publication.
From where data/document is obtainable
After the article publication, people can find the article

by searching in internet and access the data.

What processes are involved for a request to access data/document

After the article publication, people can find the article by searching in internet and access the data.

Comments