

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of whole body electrical muscle stimulation and common strengthening exercises on pain and improvement of function in women with patellofemoral pain syndrome

Protocol summary

Study aim

Comparison of the effectiveness of two treatment protocol of strengthening exercises and strengthening exercises with whole body electrical stimulation on improving pain and function in women with patellofemoral pain syndrome.

Design

Two arm parallel group randomised trial. 60 women with patellofemoral pain syndrome

Settings and conduct

This study, which will be performed in physiotherapy center of Ayatollah Taleghani Hospital in Ahvaz, 60 women with patellofemoral pain syndrome participate. Includes two groups: 1- Therapeutic exercises (doing 7 weeks of knee and hip strengthening exercises) 2- group of whole body electrical stimulation and strengthening exercises (7 weeks of electrical stimulation with exercises)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female(18-40) Pain in anterior of knee or posterior the patella in one or both knees that is exacerbated in at least 2 of the following activities: sitting too much, squatting, going up and down stairs, kneeling, jumping and running Exclusion criteria; History of previous surgery and injury on the knee joint. Having a pacemaker, implant . Pregnancy. Epilepsy

Intervention groups

The exercise group(control), include strengthening exercise hip and knee muscles, which will be based on the standard rehabilitation protocol in patients with patellofemoral pain, and the second group performs these exercises with the whole body electrical stimulation.

Main outcome variables

pain, physical performance

General information

Reason for update

Acronym

PFPS

IRCT registration information

IRCT registration number: **IRCT20220421054600N1**

Registration date: **2022-07-04, 1401/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-04, 1401/04/13**

Update count: **0**

Registration date

2022-07-04, 1401/04/13

Registrant information

Name

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Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of whole body electrical muscle stimulation and common strengthening exercises on pain and improvement of function in women with patellofemoral pain syndrome

Public title

Whole body electrical muscle stimulation in patellofemoral pain syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Young women with a gradual onset of anterior knee pain without a history of trauma for at least 6 months.

Exclusion criteria:

Any intra-articular symptoms such as ligament and meniscal injury. Existence of pain and tenderness in the patellar tendon, the internal hamstring tendon, ilio tibial band. Osgood Schlatter or Sinding Larsen-Johansson syndrome. Referral pain of hip and lumbar. History of patellar dislocation. History of previous surgery on the patellofemoral joint. Existence of signs of degeneration in radiographic finding. Taking corticosteroids and anti-inflammatory drugs. Having a pacemaker, implant. Pregnancy. Epilepsy.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People with patellofemoral pain syndrome are randomly divided into two groups include: strengthening exercises and strengthening exercises with electrical stimulation of the whole body by tossing coins.

Blinding (investigator's opinion)

Single blinded

Blinding description

Three specialist are involved in the study process. The first specialist is in charge of the evaluation, the second specialist is in charge of therapeutic interventions, and the third specialist is in charge of analyzing the results. In this study, the specialist who evaluations patient is blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Rehabilitation School

Street address

Blv Golestan,Ahvaz Town

City

Ahvaz

Province

Khouzestan

Postal code

33133 -61357

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.AJUMS.REC.1401.021

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

Pain score in the visual analogue scale

Timepoint

Measurement of pain at the beginning of the study, seven weeks and three months after starting interventions.

Method of measurement

Visual analogue scale

2

Description

Function(strength)

Timepoint

Measurement of function (strength) at the beginning of the study, seven weeks and three months after starting interventions.

Method of measurement

Dynamometer

3

Description

Function (Step down test)

Timepoint

Measurement of function (step down test) at the beginning of the study, seven weeks and three months after starting interventions.

Method of measurement

The number of repetitions

4

Description

Function(muscle endurance)

Timepoint

Measurement of function (muscle endurance) at the beginning of the study, seven weeks and three months after starting interventions.

Method of measurement

time

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Exercise therapy with whole body electrical stimulation .The treatment protocol in this group includes the knee and hip muscles strengthening : quadriceps isometric contraction, abductor and external-internal rotator muscles, single leg raising in all plane, weight training , elastic band training in all plane, lower extremity balance training(static and movable surface with tilt board) (three times per week) and whole body electrical stimulation (1.5 sessions per week : 1 session per week and in the next week 2 session per week). This protocol is performed for seven weeks .frequency of current is 50 hz, puls duration 350 micoro sescend and treatment time-15 min

Category

Rehabilitation

2

Description

Control group: In this group, common strengthening exercises of knee and hip muscles are performed for 7 weeks and with a frequency of three times a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Neda Oraki far

Street address

Taleghani hospital, Saadat Blvd, Padadshahr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant faculty members

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Neda Oraki far

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Maryam Kiani Haftlang

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Latest degree

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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

the raw data of all participant will not be published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the raw data of all participant will not be published.

When the data will become available and for how long

the raw data of all participant will not be published.

To whom data/document is available

the raw data of all participant will not be published.

Under which criteria data/document could be used

the raw data of all participant will not be published.

From where data/document is obtainable

the raw data of all participant will not be published.

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

the raw data of all participant will not be published.

Comments

the raw data of all participant will not be published.