

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Added value of calf muscles dry needling to stretching exercise in improving knee pain and function in patients with chronic patellofemoral pain

Protocol summary

Study aim

The aim of this study was to investigate the effect of to add dry needling in calf muscles to stretching exercise on improving pain and function in patients with chronic patellofemoral pain.

Design

A randomized clinical trial with parallel, controlled, single blind groups

Settings and conduct

In this clinical trial study, 36 patients with patellofemoral pain who referred to clinics affiliated to Shiraz School of Rehabilitation Sciences will be divided into two groups using a random method: the first group of stretching exercises with dry needling and The second group receive only stretching exercises.

Participants/Inclusion and exclusion criteria

This study are perform in people with patellofemoral pain who have pain for at least 3 months and their average pain during the last week is 4-7 and they have at least one trigger point in each group of gastrocnemius and soleus and peroneal muscles. And if they have special injury to the ankle and knee joint or are prohibited from using dry needling, they will be excluded from the study.

Intervention groups

Stretching Exercise Group: People with patellofemoral pain who receive only gastrocnemius, soleus and peroneal muscle stretching exercises. People do exercises 5 times a week for 10 sessions for 2 weeks. Stretching exercises with dry needling group: People with patellofemoral pain who in addition to stretching exercises of the mentioned muscles according to the routine of the control group, receive 4 sessions of dry needling twice a week for two weeks in the trigger points of gastrocnemius, soleus and peroneal muscles. Samples recruited from rehabilitation clinics of Shiraz University of Medical Sciences.

Main outcome variables

pain and function level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190909044734N3**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Leila Abbasi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Added value of calf muscles dry needling to stretching exercise in improving knee pain and function in patients with chronic patellofemoral pain

Public title

The effect of adding dry needling in calf muscles to stretching exercise in improving pain and function in patients with chronic patellofemoral pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People 18 to 45 years old with unilateral patellofemoral pain Complaints of anterior knee pain in at least 2 daily activities include: prolonged sitting, going up and down stairs, squatting, kneeling, jumping, and running. Report of pain when touching the internal and external patellar procedures and positive Clark test in knee extension and sitting position. Gradual onset of symptoms with no history of trauma or injury for at least the past 3 months. Kujala score level 80-50 with moderate disability. Have an average pain level of 4-7 on a numerical pain scale over the past week. Have at least one active or latent trigger point in each group of gastrosoleus muscles and peroneal muscles of the affected side, which is felt as a taut, sensitive and painful bundle. People with BMI=18.5-25

Exclusion criteria:

Injury of knee joint such as rupture of the meniscus or ligaments and tendons of the knee, osteoarthritis of the knee joint, dislocation of the patella Ankle injuries such as rupture of ligaments and tendons, ankle osteoarthritis, dislocation of ankle Ankle sprain in the last 6 months History of surgery and trauma to the entire lower extremity in the last 6 months Neurological disorders of the lower extremities and neuropathic pain Athletes who engage in certain sports activities at least two hours a day and three times a week People who have received physiotherapy and dry needling for patellofemoral pain in the last 6 months Contraindications to the use of dry needling: - The presence of metabolic diseases such as diabetes, rheumatic diseases - Local or systemic infections - Local ulcers on the skin - Pregnancy - Respiratory and cardiovascular problems (peripheral vascular disease, cancer, hepatitis, AIDS and any Malignancy - Taking immunosuppressive drugs - Any fear and reluctance to needle (needle phobia) - Epilepsy and mental health problems - Bleeding disorders and taking anticoagulants

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Using of randomization software, 36 numbers are considered for each case and the software defines 9 blocks of 4, from 4 to 2 people in the stretching group and 2 people in the stretching group with dry needling. They are dried and thus 36 people are completed

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who will evaluate the patients and analyze the data is completely unaware of the details of the patient grouping and the treatments performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research, Shiraz Faculty of Rehabilitation Sciences

Street address

Abiverdi Street 1, Chamran Blvd

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Postal code

1733-71345

Approval date

2022-06-15, 1401/03/25

Ethics committee reference number

IR.SUMS.REHAB.REC.1401.011

Health conditions studied**1****Description of health condition studied**

Chronic patellofemoral pain

ICD-10 code

M25.56

ICD-10 code description

Pain in knee

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention, after the end of the treatment (at the end of the second week) and two weeks after the end of the treatment as a follow-up

Method of measurement

NPRS

2

Description

Pain pressure threshold

Timepoint

Before the intervention, after the end of the treatment (at the end of the second week) and two weeks after the end of the treatment as a follow-up

Method of measurement

Pressure algometer device

3

Description

Function

Timepoint

Before the intervention, immediately after the end of the treatment (at the end of the second week) and two weeks after the end of the treatment as a follow-up

Method of measurement

Kujala questionnaire

4

Description

ROM of dorsiflexion and inversion

Timepoint

Before the intervention, immediately after the end of the treatment (at the end of the second week) and two weeks after the end of the treatment as a follow-up

Method of measurement

Goniometer

5

Description

Functional tests

Timepoint

Before the intervention, immediately after the end of the treatment (at the end of the second week) and two weeks after the end of the treatment as a follow-up

Method of measurement

Step down and anteromedial lunge tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : Stretching exercise with dry needling group: People with patellofemoral pain who in addition to stretching exercises of the gastrocnemius, soleus and peroneal muscles according to the routine of the control group, receive 4 sessions of dry needling twice a week for two weeks in the trigger points of gastrocnemius, soleus and peroneal muscles.

Category

Rehabilitation

2

Description

Control group: Stretching Exercise Group: People with patellofemoral pain who receive only gastrocnemius, soleus and peroneal muscle stretching exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Leila Abbasi

Position
Assistant Professor

Latest degree
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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
No more information

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