

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation the effect of Gluteus Medius dry needling plus conventional physiotherapy in comparison with conventional physiotherapy on pain and physical function in women with routine daily activities(non-athletic) with unilateral Patellofemoral pain syndrome

Protocol summary

Study aim

The purpose of this study is to determine The effect of using dry needling in Gluteus medius muscle on pain and function of patients with patellofemoral pain syndrome(PFPS)

Design

Two arm parallel group randomized double blind trial with blinded postoperative care and outcome assessment

Settings and conduct

After issuing ethics license from Isfahan University of Medical Sciences in clinics and physiotherapy of hospitals under the supervision of Isfahan University of Medical Sciences. The individual, with the diagnosis of PFPS, previously given by a specialist physician, enters the physiotherapy center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-athlete women; suffering from patellofemoral syndrome; with complaints of gradual anterior knee pain; at least one month; and aged between 17 and 40 years old. Non-inclusion criteria: Patients with any history of knee injury; other pathologies such as rupture of knee ligaments or meniscus.

Intervention groups

Intervention group: Dry needle in gluteus medius muscle with conventional physiotherapy for knee Control group: Conventional physiotherapy for the knee

Main outcome variables

pain - function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160408027287N3**

Registration date: **2019-10-17, 1398/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-17, 1398/07/25**

Update count: **0**

Registration date

2019-10-17, 1398/07/25

Registrant information

Name

Javid Mostamand

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-26, 1398/05/04

Expected recruitment end date

2019-10-26, 1398/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of Gluteus Medius dry needling

plus conventional physiotherapy in comparison with conventional physiotherapy on pain and physical function in women with routine daily activities(non-athletic) with unilateral Patellofemoral pain syndrome

Public title

Investigation the effects of dry needling in Gluteus medius muscle on pain and physical function in women with unilateral patellofemoral pain syndrome (PFPS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Report the pain on the anterior knee or around the patella, during at least 3 activities: up or down stairs, squatting, running, kneeling, jumping, or hopping and sitting long Non-athletic woman have unilateral syndrome with positive patellar glide test There are symptoms for at least 4 weeks Full knee range of motion without any history of injury Active trigger point in gluteus medius in opposite side of the affected knee Age of 17 to 40 years

Exclusion criteria:

Meniscal and intra articular injury collateral and cruciate ligament injury tenderness in patellar tendon, iliotibial band and pesansernous tendon patella dislocation knee inflammation the history of knee surgery pregnancy, malignancy, knee arthritis and neurologic impairment neurologic symptom in sensory, motor and reflex knee pain with ankle and foot or hip or lumbar or sacroiliac sources The presence of trigger point of the gluteus medius muscle on both sides

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Data analyster

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization of the subjects was done using a random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher has been blinded and only applies conventional physiotherapy for both groups. Data analyzer is blinded to the control and treatment group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services, Hezarjarib street, Azadi Square, Isfahan

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Province

Isfahan

Postal code

81746-73461

Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.229

Health conditions studied

1

Description of health condition studied

patellofemoral pain syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of pain

Timepoint

At the beginning of the study (before the intervention), after the end of the sixth session (the last session), 1 week after the end of the sessions

Method of measurement

visual analog scale (VAS)

2

Description

physical function

Timepoint

At the beginning of the study (before the intervention), after the end of the sixth session (the last session), 1 week after the end of the sessions

Method of measurement

Kujala Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group in addition to conventional knee physiotherapy, receives the treatment of dry needling in the gluteus-medius in side effected . Dry needle therapy is performed three sessions (once a week) at the most painful point of the muscle (active trigger point) and with 10 times the technique inside and outside.

Category

Rehabilitation

2

Description

Control group: The control group will receive only conventional knee physiotherapy, which includes: Straight leg raise for 7.5 minutes, single leg squats for a period of 7.5 minutes, and a high frequency TENS device for 15 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of Isfahan Rehabilitation Sciences Faculty

Full name of responsible person

Fereshteh Karamiani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fereshteh Karamiani

Position

Master's student of Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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