Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Dry needling effects of gastrocnemius muscle on pain, function, and dynamic balance in amateur athletes with patellofemoral pain syndrome

Protocol summary

Study aim
To investigate the effect of Gastrocnemius dry needling on athletes with patellofemoral pain syndrome

Design
Twenty four athletes with patellofemoral pain are divided into two control and intervention group with the block randomization method using the randomization.com. The study is single blinded and third phase.

Settings and conduct
In the people with patellofemoral pain, gastrocnemius muscle is on of the most important muscles that get involved and become tight. On the other hand, dry needling is an effective intervention to release muscles. Therefore, in the upcoming study, the effect of gastrocnemius muscle dry needling on athletes with patellofemoral pain will be investigated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Anterior knee pain during activities such as descending stairs, squatting, kneeling, prolonged sitting 2. Positive Clark test 3.Gastrocnemius tightness in affected side Exclusion criteria: 1.Presence conditions such as knee osteoarthritis, patellar tendonitis, bursitis 2.Referral pain from lumbar or hip 3. Contraindications of dry needling such as cardiac and coagulations disease, pregnancy, malignancy and fear of needle

Intervention groups
In the control group, physiotherapy program including TENS and quadriceps strengthening exercises including straight leg raising and single leg squat, will be performed. Intervention group, in addition to the physiotherapy mentioned, will received dry needling in gastrocnemius muscle of affected side.

Main outcome variables
Pain; function; dynamic balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240724062529N1**
Registration date: **2024-08-09, 1403/05/19**
Registration timing: **prospective**

Last update: **2024-08-09, 1403/05/19**
Update count: **0**

Registration date
2024-08-09, 1403/05/19

Registrant information
Name
Elham Tavakoli
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
2024-08-27, 1403/06/06

Expected recruitment end date
2024-11-26, 1403/09/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Dry needling effects of gastrocnemius muscle on pain, function, and dynamic balance in amateur athletes with patellofemoral pain syndrome

Public title
Dry needling effects on athletes with patellofemoral pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Amateur athletes with regular sports activity at least 2h per day 3 times per week Age between 18 and 40 years Anterior knee pain for at least 3 month, aggravated with at least 1 activities such as stair descending, squatting, kneeling or prolonged sitting Positive Clark test Gastrocnemius tightness in affected side by Silfverskiöld test VAS ≥ 30 mm in first assessment Kujala questionnaire score < 85 of 100
Exclusion criteria:
Knee osteoarthritis, patellar tendonitis, bursitis or infrapatellar fat pad Patellar fracture or dislocation history Referred pain from lumbar, hip or ankle Bilateral anterior knee pain Previous surgery in affected lower limb Contraindications of dry needling such as cardiovascular and coagulation disease, anticoagulation therapy, pregnancy, cancer, fear of needles Physical therapy for knee pain within the previous 3 months Genu valgum, genu varum, genurecurvatum and flat foot in affected limb
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: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
After the baseline assessments, the participants will be randomized into intervention or control group. randomization will be done in block method by Randomization.com. In this way, 6 blocks of 4 people will be used by assigning two by two between two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be single-blinded. In this way, another physiotherapist will do the baseline and post-treatment evaluation without knowing which patients belonged to which group (assessor blinding).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Science
Street address
Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2024-08-03, 1403/05/13
Ethics committee reference number
IR.TUMS.FNM.REC.1403.052

Health conditions studied

1

Description of health condition studied
Patellofemoral Pain Syndrome
ICD-10 code
M22.2X
ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, After the last session of intervention, One week after the last session of intervention
Method of measurement
Visual Analogue Scale

2

Description
Function
Timepoint
Before intervention, After the last session of intervention, One week after the last session of intervention
Method of measurement
The Kujala Scale

3

Description
Dynamic Balance
Timepoint
Before intervention, After the last session of intervention,

One week after the last session of intervention

Method of measurement

Dynamic Leap and Balance Test (DLBT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (12 people): In addition to three weeks physiotherapy program (TENS, quadriceps strengthening exercises), will receive dry needling on gastrocnemius muscle in affected side once a week.

Category

Rehabilitation

2

Description

Control group (12 people): will receive physiotherapy program including TENS and quadriceps strengthening exercises (straight leg raising, single leg squat) three times a week for three weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Medicine Federation of Iran

Full name of responsible person

Morteza Ahmadi

Street address

Iran Sports Medicine Federation, No. 17, Varzandeh st., South Mofatteh av., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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?

No

Title of funding source

Tehran University of Medical Science

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

Tehran University of Medical Sciences

Full name of responsible person

Behrouz Attarbashi Moghadam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts 3 months after the articles are published.

To whom data/document is available
For researchers working in academic and scientific institutions

Under which criteria data/document could be used
Researchers working in the field of sport physiotherapy

From where data/document is obtainable
Applicants for documentation can contact Elham Tavakoli via email

What processes are involved for a request to access data/document
Once they have the necessary criteria, the information will be provided to them within a month

Comments