Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the combined gluteus medius and quadratus lumborum dry needling & exercise with exercise alone on knee joint pain and function in female athletes with patellofemoral pain syndrome

Protocol summary

Study aim
The purpose of this study is to evaluate the effect of the effect of gluteus medius and quadratus lumborum muscle dry needling combined with therapeutic exercises on pain intensity, Pain threshold, function and balance in female athletes with patellofemoral pain syndrome.

Design
Two arm parallel group randomised trial with single-blind

Settings and conduct
In this clinical trial, individuals are included in the study if they are eligible and randomly assigned to one of the two intervention and control groups (each group of 20) using the Randomizer software

Participants/Inclusion and exclusion criteria
Women athletic patients with patellofemoral pain syndrome complaining gradual anterior knee pain during last 3 months and age between 18 to 45 years old are included. The patients with any previous knee trauma or other pathologies such as meniscus and ligament injuries are excluded.

Intervention groups
Minimal sample size for this study was determined as 20 patients in each group. Patients will randomly assigned either to control or intervention groups. Both groups will receive conventional physical therapy exercises for patellofemoral pain syndrome during 4 weeks (8 sessions), while the intervention group will receive gluteus medius and quadratus lumborum muscle dry needling.

Main outcome variables
Pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120411009440N20**
Registration date: **2018-08-02, 1397/05/11**
Registration timing: **prospective**

Last update: **2018-09-04, 1397/06/13**
Update count: **1**

Registration date
2018-08-02, 1397/05/11

Registrant information

Name
Soraya Pirouzi

Name of organization / entity
School of Rehabilitation Sciences, Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1626 5108

Email address
piroozis@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-05, 1397/05/14

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the combined gluteus medius and quadratus lumborum dry needling & exercise with exercise alone on knee joint pain and function in female athletes with patellofemoral pain syndrome

Public title
The effect of gluteus medius and quadratus lumborum dry needling in patients with patellofemoral pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18 to 45 years old with unilateral or bilateral patellofemoral pain syndrome; anterior or retropatellar knee pain during at least 2 following activities: prolonged sitting, ascending or descending stair,squatting, kneeling, jumping and running; pain on palpation of medial and lateral patellar facets and positive patellar grind test; an insidious onset of symptoms not related to trauma for the last 3 months; Kujula scores less than 85 out of 100; numeric rate scale scores ranging 3 to 10 during last week. having trigger point in the gluteus medius muscle in the affected side and quadratos lumbar muscle in the non-affected side

Exclusion criteria:
Other knee joint pathologies such as meniscus and ligament injuries, osteoarthritis and tendon impairments; patellar subluxations or dislocations; Sinding-Larsen disease;Osgood–Schlatter disease; pelica syndrome;ankle and knee injury; hip joint pathologies such as ligament injuries, osteoarthritis and tendon impairments; subluxations or dislocations and hip injury; referral pain from other joints including lumbar spine, hip and sacroiliac joints and spinal fractures; LBP without source of myofascial; any pain during sitting such as Coccydynia; previous knee surgery; Structural and biomechanical problems such as: Varus and Valgus knee; overweight 32< BMI Prohibition the use of dry needles such as:metabolic diseases such as diabetes, rheumatic diseases and neuromuscular diseases; pregnancy; Respiratory and peripheral vascular disease, cancer and any malignancy; Immune deficiency; Menstruation; needle phobia; Hemorrhagic diseases and the use of anticoagulant drugs; liver and kidney disease

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization tool:Statistical software

Blinding (investigator's opinion)
Single blinded

Blinding description
single blind, the assessor are not aware of the group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand Blvd., Central Building of Shiraz University of Medical Sciences

City
shiraz

Province
Fars

Postal code
713451978

Approval date
2018-07-04, 1397/04/13

Ethics committee reference number
IR.SUMS.REC.1397.326

Health conditions studied

1

Description of health condition studied
Patellofemoral disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain threshold

Timepoint
first and 8th sessions and 2 weeks after the intervention

Method of measurement
algometry

2

Description
Pain intensity

Timepoint
first and 8th sessions and 2 weeks after the intervention

Method of measurement
Numeric Rate Scale (NRS)

3

Description
Functional steping
Timepoint
first and 8th sessions and 2 weeks after the intervention
Method of measurement
Step down test

4

Description
function
Timepoint
first and 8th sessions and 2 weeks after the intervention
Method of measurement
kujula questionnaire

5

Description
balance
Timepoint
first and 8th sessions and 2 weeks after the intervention
Method of measurement
Y-Balance Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The same as control group plus gluteus medius and quadratus lumborum dry needling for 4 sessions , are given over a period of four weeks one session per weeks.The needle technique is fast in and out into the muscle tight band in three times
Category
Rehabilitation

2

Description
Control group: Exercise progresively, first week: Stretching exercises for quadriceps, hamstring (2set 15 repetition, 10 second hold); quadriceps setting in 10 degree terminal knee extension(3set 10 repetition),second week:sideling straight leg raises and hip abductors and external rotator strengthening exercise (Clamshells)(3 set, 15 repetition).third week: plank, side plank (3set 20 repetition). Fourth week: minisquat، minilung، single leg stance step down (Stairs with height 18 cm) (3set 25 repetition)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy clinic of Shiraz School of Rehabilitation
Full name of responsible person
Hanieh zarei
Street address
NO.32, Abiverdi 1 Avenue, Chamran Blvd, Shiraz
City
shiraz
Province
Fars
Postal code
7196744414
Phone
+98 71 1626 1081
Email
hanizareipt@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Basir Hashemi
Street address
Shiraz University of Medical Sciences Building, Zand Street,shiraz
City
shiraz
Province
Fars
Postal code
7196744414
Phone
+98 71 1626 1081
Email
piroozis@sums.ac.ir
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
Hanieh zarei

Position
Master science student of Physical Therapy

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
NO.32, Abiverdi 1 Avenue, Chamran Blvd, Shiraz

City
shiraz

Province
Fars

Postal code
7196744414

Phone
+7 136231831

Email
hanizareipt@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr soraya piroozi

Position
Phd of Physiotherapy

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
NO.32, Abiverdi 1 Avenue, Chamran Blvd, Shiraz

City
shiraz

Province
Fars

Postal code
7196744414

Phone
+98 71 1626 1081

Email
piroozis@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hanieh zarei

Position
Master science student of Physical Therapy

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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City
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Province
Fars

Postal code
7196744414

Phone
+7 136231831

Email
hanizareipt@gmail.com

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