

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of dry needling of trigger point around knee and hip on pain, function and proprioception in patient with knee OA

Protocol summary

Study aim

The effect of dry needling of trigger point around knee and hip on pain, function and proprioception in patient with knee OA

Design

The present study is an applied one-blind randomized clinical trial study. The sample size is based on the data obtained from a pilot study of 24 people. We use a simple sampling method and people will be randomly divided into two parallel groups of intervention and control by blocked randomization method.

Settings and conduct

Patient evaluation will be done immediately before and one day after the end of the last treatment session. It should be noted that the evaluation of patients will be done by a person who is not aware of the allocation group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age from 45 to 70 years old; severity of knee osteoarthritis ranging from 2 to 3 using Kellgren Lawrence scale; having at least one trigger point in the muscles around knee and thigh. Exclusion criteria: blood disorders like hemophilia; coagulation and thalassemia; needle phobia.

Intervention groups

Intervention group: the patients treated for one week and three sessions a week, by needling of muscles around the knee (the muscles that have Trigger point). The main physical characteristic to identify a trigger point is being painful during local touch and feeling a painful rigid bundle within the skeletal muscle that produces and distributes pain and discomfort with a continuous compression of about 10 to 20 seconds. Control group: receive no treatment and for ethical considerations they will be given a useful exercise program at the end of the project.

Main outcome variables

The outcome measures include pain (NRS scale), proprioception (photography method), balance (Star

Excursion Balance Test & Timed Up and Go test) and trigger point sensitivity (Algometer).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131225015932N14**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **prospective**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Alireza Motealleh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1626 5108

Email address

motealleh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-20, 1397/04/29

Expected recruitment end date

2018-08-20, 1397/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of dry needling of trigger point around knee and hip on pain, function and proprioception in patient with knee OA

Public title
The effect of dry needling of trigger point in patient with knee OA

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age from 45 to 70 years Severity of knee Osteoarthritis ranging from 2 to 3 using kellgren Lawrence scale Having at least one trigger point in the muscles around the knee and thigh The target knee is the more painful knee or the knee with more symptoms. If symptoms are similar in both sides the right knee will be considered as the target. The KOOS score (knee injury and osteoarthritis score) between 120-80
Exclusion criteria:
Drainage of articular fluid or corticosteroid injection in last year Any surgery, fracture or dislocation in the lower extremities and the spine Systemic diseases like diabetes Soft tissue rheumatism Active knee inflammation Any neurological disease, such as epilepsy,... (because it can affect the function and balance of the individual.) Taking anticoagulants such as aspirin and plavix Blood disorders like hemophilia, coagulation disorders and Thalassaemia Auto immune diseases Needle Phobia Lymphedema Malignancy Hepatitis Acute infection Cardiovascular diseases like heart valve problems Vestibular System Problems

Age
From **45 years** old to **70 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
The patients will be allocated to two parallel groups (control and intervention) via blocked randomization method by randomizer software. Allocation concealment will be performed via SNOSE method. (sequentially numbered , sealed, opaque envelopes)

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will be blinded to group allocation in this study. (single blind study)

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
Shiraz University of Medical Sciences, Zand street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2018-02-06, 1396/11/17
Ethics committee reference number
IR.SUMS.REC.1396.169

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M19.9
ICD-10 code description
Osteoarthritis, unspecified site

Primary outcomes

1

Description
Pain
Timepoint
Before treatment, the day after the last treatment session
Method of measurement
Numerical Rating Scale

2

Description
Sensitivity of trigger points
Timepoint
Before treatment, the day after the last treatment session
Method of measurement

Algometer

3

Description

Proprioception

Timepoint

Before treatment, the day after the last treatment session

Method of measurement

Photography method

4

Description

Balance

Timepoint

Before treatment, the day after the last treatment session

Method of measurement

Modified Star Excursion Balance Test & Timed Up and Go test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for one week and three sessions a week, they are treated with a needle in the muscles around the knee (the muscles that have Trp). The main physical characteristic to identify the trigger points is touched by a painful local nail in a rigid bundle within the skeletal muscle that produces and distributes a pain and discomfort with a continuous compression of about 10 to 20 seconds.

Category

Treatment - Other

2

Description

Control group: no treatment has been received, and in order to be ethical the research will give the group a useful exercise program at the end of the project.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy clinic of Shiraz School of Rehabilitation

Full name of responsible person

Dr. Alireza Motealleh

Street address

School of Rehabilitation Sciences, Abiverdi 1 Avenue,

Chamran Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

33669-71947

Phone

+98 71 1627 1552

Email

motealleh@sums.ac.ir

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

33669-71947

Phone

+98 71 3627 1552

Email

hashemib@yahoo.com

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

Neda Rahimi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, Abiverdi 1 Avenue,
Chamran Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

33669-71947

Phone

+98 71 1627 1552

Email

nedarahimira15273@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Alireza Motealleh

Position

Ph.d.

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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nedarahimira15273@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