Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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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