

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of dry needling and ischemic compression on the trigger points of the lower half muscles behind the knee on pain and disability and muscle and joint stiffness in knee osteoarthritis patients: randomized clinical trial single-blind

Protocol summary

Study aim

Investigating and comparing the effect of adding dry needling and ischemic pressure to routine physiotherapy on pain, muscle stiffness, knee joint stiffness, disability, pressure pain threshold and knee range of motion in patients with knee osteoarthritis

Design

The clinical trial will have 3 groups, with parallel groups, single blind, randomized, on 60 patients. For randomization, the Block Randomization method is used by the Randomization.com online site.

Settings and conduct

The study is carried out in Farhangian Central Hospital in Tehran. Patients are randomly divided into 3 intervention and control groups of 20 people. Before and after interventions, pain intensity, disability, gastrocnemius and popliteus muscle stiffness, knee joint stiffness, pressure pain threshold and knee range of motion will be measured. This study will be a single blind so that the assessor will not know about the groups allocation and other parts of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate osteoarthritis, presence of at least one trigger point, age between 50-70 years, pain level above 30 mm and below 80 mm on the VAS scale. Exclusion criteria: severe swelling of the knee, systemic disease, contraindications to dry needling, fibromyalgia syndrome, radiculopathy/myopathy

Intervention groups

1- dry needling plus routine physiotherapy 2- Ischemic pressure plus routine physiotherapy 3- Routine physiotherapy alone

Main outcome variables

Pain intensity, disability, muscle stiffness, joint stiffness, pressure pain threshold and knee range of motion

General information

Reason for update

Referee's recommendation

Acronym

IRCT registration information

IRCT registration number: **IRCT20170715035097N2**

Registration date: **2023-04-13, 1402/01/24**

Registration timing: **prospective**

Last update: **2024-12-16, 1403/09/26**

Update count: **1**

Registration date

2023-04-13, 1402/01/24

Registrant information

Name

Mohsen Shams

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-01, 1402/02/11

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of dry needling and ischemic compression on the trigger points of the lower half muscles behind the knee on pain and disability and muscle and joint stiffness in knee osteoarthritis patients: randomized clinical trial single-blind

Public title

Comparing the effectiveness of dry needling and ischemic pressure on trigger points in knee osteoarthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Mild to moderate severity of osteoarthritis (grade I-III in the Kellgren-Lawrence scale) The presence of at least one trigger point (latent or active) in the gastrocnemius and popliteus muscles based on the criteria of Travell and Simons, which can be detected by touch. Age between 50-70 years The pain level of knee osteoarthritis patients should be higher than 30 mm and less than 80 mm on the VAS scale and at least 3 months have passed since its onset. Morning joint stiffness less than 30 minutes

Exclusion criteria:

Severe inflammation/swelling of the knee Any previous fracture or surgery of the lower limb Systemic disease (such as rheumatoid arthritis or diabetes) Contraindications to using dry needling, including pregnancy, malignancy, fear of needles, bleeding disorders (such as hemophilia or thalassemia), taking antiplatelet and anticoagulant drugs Complete replacement of the knee joint on the affected side Injection of opioid analgesics or corticosteroids in the last 30 days Fibromyalgia syndrome Physical therapy or dry needling in the last 3 months Radiculopathy/myopathy

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using the block balanced randomization method. Considering that the current study has 3 groups, therefore, blocks of 6 letters are used, which is done by a site called Randomization.com. This site produces a list that is numbered from 1 to 60 according to the sample size of the study and one of the

letters A, B or C is randomly written in front of each number. Then 60 envelopes are prepared, which are numbered from 1 to 60, According to the list produced by the site, the letter A, B or C in front of each number is written on a piece of paper and placed in the corresponding envelope, and the envelope is sealed, and before starting the treatment, the first patient is given envelope number 1 and to the second patient envelope number 2 and so on. Therefore, after opening each envelope, it is determined which group each patient belongs to

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blinded to the groups allocation and other parts of the study

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of social welfare and rehabilitation sciences

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Koodakyar Blind Alley , Daneshjoo Boulevard , Evin

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1985713834

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.USWR.REC.1401.255

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes**1****Description**

Pain Intensity

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Disability

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score questionnaire

2

Description

Muscle stiffness

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Shear wave elastosonography

3

Description

Joint stiffness

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Electrogoniometer and pendulum test

4

Description

Pressure pain threshold

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Algometer

5

Description

Rang Of Motion

Timepoint

Before the intervention - immediately after the end of the intervention

Method of measurement

Standard goniometer

Intervention groups

1

Description

First intervention group: 3 sessions of dry needling twice a week on trigger points plus 10 daily routine physiotherapy sessions (Includes 20 minutes of conventional TENS with a frequency of 100 Hz and 50 microsecond duration as much as the patient feels with a hot pack on the back of the knee, quadriceps strengthening exercises, hip abductors and calf muscles)

Category

Rehabilitation

2

Description

Second intervention group: 3 sessions of ischemic compression (pressure) twice a week on trigger points plus 10 daily routine physiotherapy sessions (Includes 20 minutes of conventional TENS with a frequency of 100 Hz and 50 microsecond duration as much as the patient feels with a hot pack on the back of the knee, quadriceps strengthening exercises, hip abductors and calf muscles)

Category

Rehabilitation

3

Description

Control group: 10 daily routine physiotherapy sessions (Includes 20 minutes of conventional TENS with a frequency of 100 Hz and 50 microsecond duration as much as the patient feels with a hot pack on the back of the knee, quadriceps strengthening exercises, hip abductors and calf muscles)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian Central Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

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Position

PhD Student of Physiotherapy

Latest degree

Master

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