Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 21 7739 2705

Email address

mo.shams@uswr.ac.ir

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
Street address
Koodakyar Blind Alley , Daneshjoo Boulevard , Evin
City
Tehran
Province
Tehran
Postal code
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 Osteoartritis 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 plus10 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

Mohsen Shams

Street address

Imam Khomeini square, next to Fayaz Bakhsh bus terminal

City

Tehran

Province

Tehran

Postal code

1114655111

Phone

+98 21 6672 7313

Fax

Email

dfm@tehranedu.org

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Hamidreza Khankeh
Street address
Koodakyar Blind Alley, Daneshjoo Boulevard, Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7173 2832
Fax
Email
ha.khankeh@uswr.ac.ir
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
Mohsen Shams
Position
PhD Student of Physiotherapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Koodakyar Blind Alley, Daneshjoo Boulevard, Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7736 4525
Email
mohsenshams48@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mohsen Shams
Position
PhD Student of Physiotherapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Koodakyar Blind Alley, Daneshjoo Boulevard, Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7739 4525
Email
mohsenshams48@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mohsen Shams
Position
PhD Student of Physiotherapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Koodakyar Blind Alley , Daneshjoo Boulevard , Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 7739 4525
Email
mohsenshams48@yahoo.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