

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of physiotherapy and physiotherapy with dry needling on pain, Range of motion, physical function, functional performance and the effectiveness of treatment in patients with primary knee osteoarthritis.

Protocol summary

Study aim

The effect of adding dry needle on trigger points to routine physiotherapy program on pain, range of motion, physical function, functional performance and effectiveness of treatment in patients with primary knee osteoarthritis.

Design

Clinical trial with control group, parallel groups, blinded, randomized, on 28 patients.

Settings and conduct

People with primary osteoarthritis of the knee after evaluation are randomly divided into two groups: physiotherapy and physiotherapy with dry needling. Individual background information will be recorded. Individuals in both groups receive 12 session of treatment for 4 weeks. The place of intervention: Tehran, Gamino physiotherapy center Blinding: participants and outcome assessors

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants aged 40 years or older with knee pain and dysfunction, Diagnosis of primary knee osteoarthritis (Kellgren-Lawrence 1-3), At least one active or latent myofascial trigger point ipsilateral to the painful knee(s), pain of at least 2 on the NRS scale for more than 3 months. Exclusion criteria: Suffering from other conditions that could cause myofascial or neuropathic pain in the lower limb, Previous total replacement, Any other surgical procedure of the lower limbs in the previous 6 months, Myopathy or lumbosacral neuropathy, Physical therapy, acupuncture or other treatments for the painful knee in the last 6 months, Inflammatory joint disease such as rheumatoid arthritis, Serious trauma or systematic disease

Intervention groups

Intervention group: Routine physiotherapy and dry needling Control group: Routine physiotherapy

Main outcome variables

Pain intensity on the NRS scale; Knee joint range of motion with goniometer; Physical function with WOMAC questionnaire; Functional performance with TUG test; The effectiveness of treatment with GROC scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210314050704N1**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Mahdie Morshedlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4221 4227

Email address

morshedloum981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of physiotherapy and physiotherapy with dry needling on pain, Range of motion, physical function, functional performance and the effectiveness of treatment in patients with primary knee osteoarthritis.

Public title

The effect of dry needling on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants aged 40 years or older with knee pain and uni- or bilateral dysfunction Diagnosis of primary knee osteoarthritis based on clinical and radiographic findings (Kellgren-Lawrence 1-3) At least one active or one latent myofascial trigger point elicited by palpation ipsilateral to the painful knee(s) Pain of at least 2 on the NRS scale for more than 3 months

Exclusion criteria:

Suffering from other conditions that could cause myofascial or neuropathic pain in the lower limb, such as lumbar radiculopathy, saphenous nerve entrapment, or paresthetica meralgia Previous total replacement of the same knee or both knees Any other surgical procedure of the lower limbs in the previous six months Medical record for myopathy or lumbo-sacral neuropathy physical therapy, acupuncture or other treatments for the painful knee in the last 6 months Inflammatory joint disease such as rheumatoid arthritis Serious trauma or systematic disease

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization using closed envelopes so that the number of samples, gender and unilateral or bilateral osteoarthritis are equal in two groups. The 4-volume random block allocation method will be used. All possible 4 permutations will be listed in two groups (permutations 1 to 6 are as follows) A is the intervention group and B is

the control group: 1-AABB 2-ABAB 3-BAAB 4-BABA 5-BBAA 6-ABBA Then, from a random number table with a random starting point, 6 numbers between 1 and 6 will be randomly selected (either using software or randomize.com). For example, if the 6 random numbers obtained are 3 5 4 3 4 6 , It will mean that the first four people similar to block 3, the second four people similar to block 5 and ... will be allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be performed in a double-blind manner and the blinding includes a physiotherapist who performs the pre- and post-treatment evaluation in addition to the person who analyzes the data.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Faculty of Paramedical Sciences, Mashhad University of Medical Sciences, Azadi Sq

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

IR.MUMS.FHMPM.REC.1401.002

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

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain intensity in Numeric Rating Scale index

Timepoint

Before and after the intervention

Method of measurement

Numeric Rating Scale index

Secondary outcomes

1

Description

Knee joint range of motion

Timepoint

Before and after the intervention

Method of measurement

Goniometer

2

Description

physical function

Timepoint

Before and after the intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

3

Description

Functional performance

Timepoint

Before and after the intervention

Method of measurement

Timed Up and Go test

4

Description

The effectiveness of treatment

Timepoint

After the intervention

Method of measurement

Global Rating of Change scale

Intervention groups

1

Description

Intervention group: Physiotherapy with dry needling. Participants in this group receive 12 sessions (3 times a week) of routine physiotherapy (Electrotherapy, manual therapy and exercise therapy) with dry needling at the trigger points of the muscles around the knee and hip.

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy. Participants in this group receive 12 sessions (3 times a week) of routine physiotherapy (Electrotherapy, manual therapy and exercise therapy).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Gamino physiotherapy center

Full name of responsible person

Mona Nowrouzi

Street address

No. 10, Ashkan building, Baghdarnia Ave, East Farjam Blvd, Tehranpars

City

Tehran

Province

Tehran

Postal code

1681984111

Phone

+98 21 7729 5929

Email

Morshedloun981@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Qureshi building, Daneshgah Ave., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

ghayourm@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahdie Morshedlou
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
No. 862, Manzari Ave., West Farjam Blvd., Narmak.,
Tehran Town
City
Tehran
Province
Tehran
Postal code
1681984111
Phone
+98 51 4326 3656
Email
MorshedlouM981@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Asghar Hoseini
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Mashhad University of Medical Science, Vakilabad
Blvd., Mashhad Town
City
Mashhad
Province

Razavi Khorasan
Postal code
9185763788
Phone
+98 51 3882 7029
Fax
+98 51 3884 6728
Email
Hosseiniha@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahdie Morshedlou
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
No. 862, Manzari Ave., West farjam Blvd., Narmak,
Tehran Town
City
Tehran
Province
Tehran
Postal code
1681984111
Phone
+98 51 4326 3656
Email
MorshedlouM981@mums.ac.ir

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