Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 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 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

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

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Mahdie Morshedlou
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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 randomaize.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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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

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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