

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of hamstring muscle dry needling with routine physiotherapy on pain , flexibility and function of patients with knee osteoarthritis

Protocol summary

Study aim

The effectiveness of hamstring muscle dry needling with routine physiotherapy on pain ,flexibility and function in patients with knee osteoarthritis

Design

Randomized controlled trial, parallel group design of 38 patients, single blinded, randomization will be computerized with concealed randomization sequence carried out at "www.randomizer.org".

Settings and conduct

Conventional physiotherapy program includes use of electrical stimulation current for 25 minutes, manual therapy including patella mobilization, traction and anterior-posterior and lateral gliding of tibiofemoral joint and exercise therapy that increases the number and difficulty of exercises every week for all participants. and the dry needling treatment in the intervention group will be performed on 6 fixed points of the hamstring. Both groups will have three sessions a week for 10 sessions at Dr. Hashem Nejad's clinic in Tehran. Also, this The study will be single-blinded and the examiner will be blinded to the grouping

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mild to moderate knee osteoarthritis diagnosis based on KL scale(grade 2 and 3) Reduced flexibility of Hamstring muscle(according to SLR and 90-90 KET) Exclusion criteria: Fear of dry needles

Intervention groups

Treatment groups include 2 groups of OA patients equal in number, in intervention group patients will receive routine physiotherapy plus dry needling of Hamstring muscle and in the other group as the control group the participant will receive routine physiotherapy.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141216020330N2**

Registration date: **2024-04-21, 1403/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-21, 1403/02/02**

Update count: **0**

Registration date

2024-04-21, 1403/02/02

Registrant information

Name

Ali Amiri

Name of organization / entity

School of Rehabilitation Sciences of Iran University,

Country

Iran (Islamic Republic of)

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amiri.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-02, 1403/01/14

Expected recruitment end date

2024-06-18, 1403/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of hamstring muscle dry needling with routine physiotherapy on pain , flexibility and function of patients with knee osteoarthritis

Public title

The effectiveness of dry needling in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

mild to moderate knee osteoarthritis diagnosis, grade 2-3 of KL(Kellgren-Lawrence) scale Reduced flexibility of Hamstring muscle Pain score of Min 2 units and Max 7 units of NPRS

Exclusion criteria:

Acute inflammation and swelling in knee joint History of fracture in vertebral column or lower extremity in past 3 months History of surgery in any of lower extremities in past 3 months History of previous surgery in painful and osteoarthritic knee History of physiotherapy, acupuncture or intra-articular injection treatment through past 3 months Uncontrolled systemic or background disease like Diabetic or Rheumatoid Aethritis limiting activities of daily living Immune deficiency disease bleeding disorder ex: Hemophilia or Thalassemia Fear of dry needles Having at least 2 neurological signs Cancer Pregnancy

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trail, blocked randomization process will be used. there will be blocks of 4 in which the number of participants in each treatment group will be equal in blocks. The website"www.randomizer.org" will be used to create the blocks, blocks would be 6 series of 4 including the A and B letters. Letter A for the dry needling group and letter B standing for the control group. according to the calculated sample size, for selection of the blocks we will roll the dice and this randomized selection will repeat for 10 times.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study assessor blinding method will be used, then the study will be single-blinded in the way that the assessor will not have any information about grouping of the participant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of medical sciences

Street address

Hemmat highway next to Milad tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-07-23, 1402/05/01

Ethics committee reference number

IR.IUMS.REC.1402.365

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee, Hamstring, Flexibility and Dry needling

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and after 10 sessions of intervention

Method of measurement

Numeric Pain Rating Scale

Secondary outcomes

1

Description

Flexibility

Timepoint

Before intervention and after 10 sessions of intervention

Method of measurement

Measuring range of motion using goniometry by Straight Leg Raising Test and Active/Passive Knee Extension Test.

2

Description

Function

Timepoint

Before intervention and after 10 sessions of intervention

Method of measurement

Timed Up and Go Test, Knee Injury and Osteoarthritis Outcome Score questionnaire

Intervention groups

1

Description

Intervention group: including 10 sessions of treatment ,3 sessions per week, patients will receive routine physiotherapy as electrical stimulation and mobilization manual therapy and therapeutic exercise and in 5 session as every other day the participants will have dry needling on 6 specific points of Hamstring muscle

Category

Treatment - Other

2

Description

Control group: including 10 sessions of treatment ,3 sessions per week, patients will receive routine physiotherapy as electrical stimulation and mobilization manual therapy and therapeutic exercise.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Hashemnejad's clinic

Full name of responsible person

Dr. Ali Amiri

Street address

Faculty of rehabilitation, Iran university of medical sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Ali Amiri

Street address

Rehabilitation school of Iran university,Tehran, Mirdamad boulevard, Madar square, ShahNazari street, Madadkaran street

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Ali Amiri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying participants

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Everyone who conducts research on clinical studies can request access to documents and non-identifiable data for any type of statistical analysis related to the studies.

From where data/document is obtainable

In order to access the documents, the applicants can visit the Faculty of Rehabilitation Sciences of the University of Iran, located in Tehran, Mirdamad Square, Mader Square, Shahid Shah Nazari Street, or contact them via email at amiri.a@iums.ac.ir.

What processes are involved for a request to access data/document

After requesting documents, the applicant can receive the information within a week by coordinating through communication channels.

Comments