

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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)

##### Phone

+98 982122228052

##### Email address

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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Not used                                                        |
| <b>Scientific title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Assignment</b>                                               |
| The effectiveness of hamstring muscle dry needling with routine physiotherapy on pain , flexibility and function of patients with knee osteoarthritis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Parallel                                                        |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Other design features</b>                                    |
| The effectiveness of dry needling in knee osteoarthritis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                 |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Secondary Ids</b>                                            |
| Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | empty                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Ethics committees</b>                                        |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>1</b>                                                        |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Ethics committee</b>                                         |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Name of ethics committee</b>                                 |
| 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 | Ethics committee of Iran university of medical sciences         |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Street address</b>                                           |
| From <b>45 years</b> old to <b>65 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Hemmat highway next to Milad tower                              |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>City</b>                                                     |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Tehran                                                          |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Province</b>                                                 |
| N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Tehran                                                          |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Postal code</b>                                              |
| <ul style="list-style-type: none"> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 1449614535                                                      |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Approval date</b>                                            |
| Target sample size: <b>38</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2023-07-23, 1402/05/01                                          |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Ethics committee reference number</b>                        |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | IR.IUMS.REC.1402.365                                            |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Health conditions studied</b>                                |
| 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.                                                                                | <b>1</b>                                                        |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Description of health condition studied</b>                  |
| Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Knee osteoarthritis                                             |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>ICD-10 code</b>                                              |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                              | M17                                                             |
| <b>Placebo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>ICD-10 code description</b>                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Osteoarthritis of knee, Hamstring, Flexibility and Dry needling |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Primary outcomes</b>                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>1</b>                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Description</b>                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Pain                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Timepoint</b>                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Before intervention and after 10 sessions of intervention       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Method of measurement</b>                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Numeric Pain Rating Scale                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Secondary outcomes</b>                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>1</b>                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Description</b>                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Flexibility                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Timepoint</b>                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1545913487

#### Phone

+98 21 2222 7124

#### Email

amiri.a@iums.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1545913487

#### Phone

+98 21 2222 7124

#### Email

Amiri.a@iums.ac.ir

### 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

#### Street address

Faculty of Rehabilitation Sciences, University of Iran

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Tehran

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## Person responsible for scientific 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**

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## Person responsible for updating data

### 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**

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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