Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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 Rhumatoid 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 recieve 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
City
Tehran
Province
Tehran
Postal code

1545913487

Phone
+98 21 2222 7124

Email
amiri.a@iums.ac.ir

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
Physiotherapy

Street address
Faculty of Rehabilitation Sciences, University of Iran

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 7124

Email
amiri.a@iums.ac.ir

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
Physiotherapy

Street address
Faculty of Rehabilitation Sciences, Iran university of medical sciences

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 7124

Email
amiri.a@iums.ac.ir

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