Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

A comparative study of lateral hamstring strengthening versus overall hamstring strengthening on pain, disability, and quality of life, and foot loading pattern in patients with primary osteoarthritis and varus deformity: randomized clinical trial

Protocol summary

Study aim

The purpose of this study is to compare the effect of exercise with the aim of increasing the activity of external hamstring, compared to the overall strengthening of hamstring on pain, disability and quality of life in patients with knee osteoarthritis.

Design

Patients will be allocated into two groups based on simple randomization using sealed envelope. With alpha 0.05 and beta 0.20 (80% power), at least 20 people in each group will be required.

Settings and conduct

Physical Therapy clinic of Qaem Hospital

Participants/Inclusion and exclusion criteria

People with knee osteoarthritis will be confirmed by an orthopedic surgeon. Patients are randomly divided into two groups of novel physiotherapy (external hamstring enhancement) and conventional physiotherapy (general hamstring enhancement) based on inclusion and exclusion criteria.

Intervention groups

Treatment will be performed in four consecutive weeks and three sessions per week. Each session includes 20 minutes of electrotherapy, 5 minutes of warm-up exercise, 5 minutes of aerobic exercise and 35 minutes of therapeutic exercise. The intervention group will perform strengthening exercises for quadriceps and hamstring muscle including isometric exercises, hamstring curl, hamstring bridge, standing and sitting knee flexion and hamstring curl with the ball. In the intervention group, all therapeutic exercises related to hamstring are performed with external rotation of the tibia. Also in this group, we focus the stretching of the hamstring muscle on its inner part.

Main outcome variables

KOOS, OAKHQOL, Tegner activity scale and pain score based on VAS criteria

General information

Reason for update

Acronym

MOAS

IRCT registration information

IRCT registration number: **IRCT20161221031506N5**
Registration date: **2021-04-15, 1400/01/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-15, 1400/01/26**
Update count: **0**

Registration date

2021-04-15, 1400/01/26

Registrant information

Name

Salman Nazary-Moghadam

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-10-21, 1400/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of lateral hamstring strengthening versus overall hamstring strengthening on pain, disability, and quality of life, and foot loading pattern in patients with primary osteoarthritis and varus deformity: randomized clinical trial

Public title

Comparative effect of two hamstring strengthening methods in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Knee pain on last six months. Pain scale (VAS) should be higher than 4 out of 10. OA patients will have Knee varrus deformity, knee crepitus, and significant limited ROM. Graded 2, and 3 based on Kellgren and Lawrence scale.

Exclusion criteria:

Any knee alignment corrective surgery Candidate for joint replacement surgery Any severe change in patient's gait due to pain and limited ROM ligament instability (Grade 3) The involvement of the patellofemoral joint or the lateral femoral condyle is greater than the medial condyle (diagnosed by X-ray) Any disorders that limit daily movements and activities Corticosteroids usage for the knee pain in the last three months Use assistive devices such as knee orthoses and walker Patients with varrus deformity (grade 1, and 3) Cognitive problems diagnosed using EMMSE questionnaire Spinal stenosis, and lumbar disc herniation

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be the block randomization method and based on that, the randomization unit will be individual. Randomization will be done using a sealed envelope. The grouping will be done by the secretary of the physiotherapy department. The secretary of the physiotherapy department will select a card from the envelope after referring the person to the physiotherapy department. The patients will be assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessor will be blinded from the patient’s grouping. The statistical analysis will be performed by one of authors who blinded about the label of grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Head Office of Mashhad University of Medical Science, Qoreishi Center, Daneshgah st., Mashhad, Iran

City

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Province

Razavi Khorasan

Postal code

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Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.MUMS.REC.1399.618

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description

Pain

Timepoint

At the time of referral - after 12 sessions of treatment - one month after treatment

Method of measurement

visual analog scale

2

Description
Disability
Timepoint
Pre-treatment, Immediately after completion of treatment - one month after completion of treatment
Method of measurement
Based on the KOOS questionnaire

3

Description
Disability
Timepoint
Pre-treatment, Immediately after completion of treatment - one month after completion of treatment
Method of measurement
Tegner activity scale questionnaire

4

Description
Quality of life
Timepoint
Pre-treatment, Immediately after completion of treatment - one month after completion of treatment
Method of measurement
OAKHQOL questionnaire

Secondary outcomes

1

Description
Foot loading pattern (medial-to-lateral COP index(MLCOPi))
Timepoint
At the time of referral - after 12 sessions of treatment
Method of measurement
Using a foot scan device

Intervention groups

1

Description
Intervention group: All hamstring therapy exercises in this group will be performed with external rotation of the tibia and the stretch will focus on medial hamstring muscle.
Category
Rehabilitation

2

Description
Control group: In this group, hamstring exercises will be applied on the muscle in general and the hamstring muscle will be stretched completely.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical Therapy Clinic of Ghaem Hospital
Full name of responsible person
Mr Javad Zarandi
Street address
First floor, Narjes building, Qaem Hospital-Dr. Shariati Square, beginning of Ahmadabad Avenue, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Personal Grant (Dr Salman Nazary-Moghadam)
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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

Hamed Mamipour Gharanjick

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for updating data

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All reports will be reported in one research paper. Raw data will be delivered to researchers only for meta analysis.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

For researchers

Under which criteria data/document could be used

Only for meta-analysis

From where data/document is obtainable

Nazary_salman@yahoo.com

What processes are involved for a request to access

data/document

The response will be sent 3 months after considering the researcher's request.

Comments