

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the efficacy of three protocols of Neuromuscular Electrical Stimulation (NMES), exercise therapy and NMES combined with exercise therapy on pain, quadriceps muscle thickness, and physical function of patients with knee osteoarthritis: A controlled randomized trial with a three-month follow-up

Protocol summary

Study aim

Determine the effectiveness of three protocols of neuromuscular electrical stimulation, exercise therapy and neuromuscular electrical stimulation and combined exercise therapy on pain, quadriceps muscle atrophy, vastus medialis muscle thickness, and physical function in patients with primary knee osteoarthritis

Design

In this study, three groups will be treated in parallel. First, the checklist of the research is completed. Then, other clinical, functional and sonographic evaluations will be performed.

Settings and conduct

This study will be performed on patients with knee osteoarthritis at Rasool Akram Hospital Sports Medicine Clinic. In this study, the assessor and statistician analyzer are going to be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primary osteoarthritis (OA); OA of the knee joint; Female gender; Age between 50-75 years; BMI equal to or less than 30. Non-inclusion criteria: History of the neuromuscular disease; Bone implants; Participating in exercise therapy and physical therapy programs in the recent three months; history of knee intra-articular injection during last 6 months.

Intervention groups

Intervention group 1: Interferential Therapy for 12 sessions to strengthen their quadriceps muscle.
Intervention group 2: In addition to NMES will also receive the therapeutic exercises program. Control group: Exercise therapy or control group (CL)- An exercise protocol for the OA patients consisted of five exercises.

Main outcome variables

Pain; Active knee flexion range of motion; The circumference of the thigh; The thickness of the Vastus Medialis muscle; Physical Function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101228005486N7**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Azar Moezy

Name of organization / entity

Iran university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the efficacy of three protocols of Neuromuscular Electrical Stimulation (NMES), exercise therapy and NMES combined with exercise therapy on pain, quadriceps muscle thickness, and physical function of patients with knee osteoarthritis: A controlled randomized trial with a three-month follow-up

Public title

Exercise therapy and NMES in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary OA of the knee joint grade 2, 3 according Kellgren and Lawrence scale Female gender Age between 50-75 years old Knee pain for at least six months and with intensity 3 on the VAS scale in activities such as getting up and downstairs, sitting and squat No history of knee intra-articular injection in the past six months Referral from a specialist No history of acute traumatic injuries approved by the referral physician No history of previous surgery or injury in the knee joints and lower extremities BMI equal or less than 30 Patient's consent to participate in the research Normal mental state

Exclusion criteria:

History of neuromuscular disease Bone implants History of new fractures in lower limbs Participating in exercise therapy and physical therapy programs in the recent three months History of chronic disease and generally any disease or conditions that known to affect the investigation Malignant tumors

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will randomly be assigned to three treatment groups employing a block randomization method with blocks of size three, produced by PASS software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the assessor is going to be blinded to the study groups. The outcomes will be evaluated pre and post-intervention by a sports medicine assistant who will be blind about the presence of patients within the groups. Furthermore, the sonography of thigh muscles is done by a sports medicine specialist who won't be aware of the patient groups. Similarly, the data obtained from the study are going to be analyzed by a statistician who isn't aware of the patient groups.

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

Iran University Of Medical Sciences, next to Milad Tower, Hemat highway

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Tehran

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Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2019-11-17, 1398/08/26

Ethics committee reference number

IR.IUMS.FMD.REC.1398.351

Health conditions studied**1****Description of health condition studied**

Primary knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Pain

Timepoint

Pre-intervention and Post-intervention

Method of measurement

VAS pain scale

2

Description

Active knee range of flexion

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Goniometry

3

Description

The circumference of the thigh

Timepoint

Pre-intervention and Post-intervention

Method of measurement

With centimeter tape

4

Description

Muscle strength of knee extensors

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Manual Muscle Testing

5

Description

Thickness of Vastus Medialis muscle

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Sonography

Secondary outcomes

1

Description

Functional Activity

Timepoint

Pre -intervention and Post -intervention

Method of measurement

Timed Up & Go Test and Six-Minute Walk Test

Intervention groups

1

Description

First intervention group: The Patients in Neuromuscular Electrical Stimulation (NMES) will be treated with Interferential Therapy for 12 sessions (three sessions per week) to strengthen their quadriceps muscle. In this study, Pre-Modulated IF two-pole currents will be used by BTL-4825 S Topline combined electrotherapy system .

Category

Rehabilitation

2

Description

Second intervention group: The Patients in this group in addition to Neuromuscular Electrical Stimulation (NMES) similar to the first intervention group will also receive the therapeutic exercises program of the control group .

Category

Rehabilitation

3

Description

Control group: Exercise protocol for the patients in the control group consisted of five exercises:1.Static contraction of the quadriceps femoris in a supine position - The patient is asked to lie in the supine position and statically contract the thigh muscles. It will be done for each leg in three sets of 10 repetitions and the duration of static contraction is 10 seconds. 2. Straight legs raising (SLR) in a supine position - The patient is asked to lie in the supine position with one knee in flexed position and raise the other leg straightly. It will be done for each leg in three sets of 10 repetitions and keeping SLR with a ten- second hold. 3.Terminal knee extension n a supine position - The patient is asked to lie in the supine position with one pillow under one of the knees; then the patient should try to extend the flexed knee at the terminal range. In the first two weeks, it will be done in three sets of 10 repetitions with a ten- second hold. 4.Static contraction of hip adductors- The patient is asked to lie in the supine position with the knee flexed and one pillow between the thighs. The patient is asked to press the thighs into the pillow.The exercise will be done in three sets of 10 repetitions for the legs in the first two weeks with a 10-second hold. 5.Wall-sit-The patient is asked to lean against the wall and spread his legs as wide as his shoulders. Then bend your knees slowly to 90 degrees flexion and hold this position for 10 seconds. This exercise will be done in three sets of 10.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Dr Soheila Masoudi

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Sponsors / Funding sources

1

Sponsor

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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
Dr Soheila Masoudi
Position
Sports Medicine Assistant
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to ethical standards, The participants have been promised that the information of this research will remain confidential in their written consent form.

Study Protocol

Yes - There is 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

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

Not applicable

Title and more details about the data/document

A portion of the data, such as data on the main outcome or like that can be shared.

When the data will become available and for how long

One year after the publication of articles related to the research project

To whom data/document is available

The researchers and specialists working in universities and health centers

Under which criteria data/document could be used

Analysis on the delivered data after obtaining permission from the researchers

From where data/document is obtainable

Dr Azar Moezy -Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan Ave, Zip code:14455613131,Tehran.

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

The applicant of the data file should send a request to the researcher via an email and the researcher will inform the applicant after negotiating with other research colleagues, and this process will take a maximum of one month.

Comments