Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 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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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
City
Tehran
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Postal code
۱۴۴۹۶۱۴۵۳۵
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
Goniometery

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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Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh street, Shahrara, Sattarkhan street
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Sponsors / Funding sources

1

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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
Sport Medicine
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Person responsible for updating data

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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