Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the short-term effects of two exercise programmes on pain, thigh muscles atrophy, function and the thickness of Vastos Medialis and Lateralis in patients with knee osteoarthritis.

Protocol summary

Study aim
Comparison of short-term effects of two therapeutic exercise protocols on pain, hip muscle atrophy, function and the thickness of Vastos Medialis and Lateralis in patients with knee osteoarthritis

Design
First, a summary of the research program is presented for participants, then the checklist of the research, which includes questions about demographic information and the medical history, as well as questions about the intensity of knee pain, is completed by the researcher. Then, other clinical, functional and sonographic evaluations will be performed.

Settings and conduct
Sports Medicine Clinic - Hazrat Rasoul Akram Hospital

Participants/Inclusion and exclusion criteria
The participants included women with knee osteoarthritis who are randomly assigned to one of the Proposed Exercise Therapy (intervention group) and Conventional Exercise Therapy(control group).

Intervention groups
- Proposed Exercise Therapy (PET)Group - Conventional Exercise Therapy (CET) Group

Main outcome variables
Pain; Active knee flexion range of motion; The circumference of the thigh; The thickness of the thigh muscles,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101228005486N6**
Registration date: **2019-05-20, 1398/02/30**
Registration timing: **registered_while_recruiting**
Last update: **2019-05-20, 1398/02/30**
Update count: **0**

Registration date
2019-05-20, 1398/02/30

Registrant information

Name
Azar Moezy

Name of organization / entity
Iran university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2446

Email address
moeziazr@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the short-term effects of two exercise programmes on pain, thigh muscles atrophy, function and the thickness of Vastos Medialis and Lateralis in patients with knee osteoarthritis.

Public title
Therapeutic exercise 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; Suffering from knee pain for at least six months and with intensity 3 on the VAS scale in activities such as getting up and down stairs, 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: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of the subjects was done by using a block random sampling; A: Proposed Exercise Therapy Group (PET) B: Conventional Exercise Therapy Group(CET) - Block 1: AABB - Block 2: ABAB - Block 3: BBAA - Block 4: BABA - Block 5: ABBA - Block 6: BAAB
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the assessor will be blinded to the study groups. The outcomes will be evaluated pre and post intervention by a sports medicine assistant who will be blind to the presence of patients in the groups.about the presence of patients in the groups. Furthermore, the sonography of thigh muscles is done by a sports medicine specialist who will not be aware of the patient groups. Similarly, the data obtained from the study will be analyzed by a statistician who is not 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, Hemat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2018-05-22, 1397/03/01
Ethics committee reference number
IR.IUMS.FMD.REC.1397.214

Health conditions studied

1

Description of health condition studied
Primary knee osteoarthritis
ICD-10 code
M17.0 - M1
ICD-10 code description
Gonarthrosis [arthrosis of the 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

Thickness of the muscles of Vastus Lateralis and Medialis

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

Intervention or Proposed Exercise Therapy Group (PETG): The exercises protocol proposed for the patients with knee osteoarthritis (KOA) is designed based on the studies that all seek to find the best way to strengthen the quadriceps femoris by employing positions in which there is a selective Vastus Medialis Oblique (VMO) activity. It's worth noting that the researchers have not yet had a consensus on this condition, and this is why the study will try to examine the impact of these positions on KOA patients. 1. Straight legs raising (SLR) in a sitting position (while leaning against the wall) with ankle dorsiflexion - for each leg in the first two weeks, which will be done in two sets of 10 repetitions in each session with five second-hold. In the second two weeks, it will be done in three sets. 2. Straight legs raising (SLR) in a sitting position with the external rotation of the thigh and a five second hold - for each leg in the first two weeks will be done in two sets of 10 in each session. In the second two weeks, it will be done in three sets ten repetition. In the first week of this exercise will be done without any resistance, and after the second week a suitable weight cuff will be added. 3. Straight legs raising (SLR)with ankle dorsiflexion - The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks, with a five-second hold. In the second two weeks, it will increase to three sets. To do this exercise, the patient is asked to lie supine while one of the knees is bent, then do SLR. In the first week of this will be done without any resistance in three sets of ten, and after the second week a suitable weight cuff will be added. 4. Static contraction of the quadriceps femoris in a standing position - The patient is asked to stand in the front of a wall, with a flexible ball behind his knee, the patient is asked to statically contract the thigh muscles and push the ball to the wall. It will be done for each leg in the first two weeks in two sets of 10 repetitions and in the last two weeks in three .the duration of static contraction is 5 seconds. 5. Static contraction of the quadriceps femoris with ankle dorsiflexion – It will be performed in two sets of 10 repetitions for each leg in the first two weeks with a five-second hold. In the second two weeks, the exercise sets will be increased to three. The patient is asked to statically contract the thigh muscles with ankle dorsiflexion while a small pillow is under the patient's knee. 6. Straight legs raising (SLR) along with the hip adduction- The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. To do this exercise, the patient is asked to lie supine, and then do SLR with hip adduction. In the first week of the exercise will be done without any resistance and after the second 2-week a suitable weight cuff will be added. 7. Straight legs raising (SLR) along with the hip external rotation-The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold.In the second two weeks, the exercise sets will be increased to three.To do this exercise, the patient is asked to lie supine, and then do SLR with hip external rotation.In the first week of the exercise will be done without any resistance and after the second 2-week a suitable weight cuff will be added. 8. Static contraction of hip adductors-The exercise will be done in two sets of 10 repetitions for the legs in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 9. The resisted exercise of the quadriceps femoris with ankle dorsiflexion- After determining the proper weight, the exercise will be done in a set with 10 repetitions and the duration of holding it will be 5 seconds, which will be accompanied by the ankle dorsiflexion. In the second week , it will be done in two sets of 10 repetition, and in the last two weeks, it will increase to three sets. 10. Terminal knee extension with theraband- The patient is asked to stand while theraband is around his knee; when the theraband pulls the knee forward, the patient should try to extend the knee at the terminal range. In the first two weeks, it will be done in two sets of 10 repetitions and in the last two weeks, it will be increased to three sets. 11. Leg press-The patient is asked to sit on leg press machine while pushing a pillow which is between the thighs and press leg at the terminal 30 degrees of the extension. In the first week, it will be done in one set of 10 repetitions, in the second week it will be done in two sets of 10 repetitions and in the last two weeks, it will be increased to three sets. 12. Heel drop - The patient is asked to stand in front of a step to a height of 30 cm and step up and down for each leg in three direction; front, lateral and back.In the first week, it will be done in one set of 10 repetitions, in the second week it will be done in two sets of 10 repetitions and in the last two weeks, it will be increased to three sets. 13. Mini squat with isometric hip adduction -The patient is asked to do mini squat while pushing a ball between the thighs.In the first two weeks,it will be done in two sets of 10 repetitions and in the last two weeks, it

will be increased to three sets. 14. Mini squat on a wedge - The patient is asked to do mini squat while standing on a ramp (30 degrees slope). In the first two weeks,it will be done in two sets of 10 repetitions and in the last two weeks, it will be increased to three sets. 15. Forward lunge - The patient is asked to do forward lunge.In the first week, it will be done in one sets of 10 repetitions,in the second week it will be done in two set of 10 repetitions and in the last two weeks, it will be increased to three sets.

Category

Rehabilitation

2

Description

Control group: Exercise protocol for patients with knee osteoarthritis for patients in the control group - 1. Straight legs raising (SLR) in a supine position - It will be done for each leg in two sets of 10 repetitions in each session in the first two weeks and keeping SLR with a five- second hold. In the second two weeks, it will be done in three sets. 2. Straight legs raising (SLR) with weight cuff - It will be done for each leg in two sets of 10 in each session in the first two weeks with a five-second hold, In the second two weeks, it will be done in three sets of 10 repetitions. In the first week, this exercise will be done without any resistance, and after the second week, a suitable weight cuff will be added. 3. 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 the first two weeks in two sets of 10 repetitions and in the last two weeks in three sets of 10 repetitions. The duration of static contraction is 5 seconds. 4. Static contraction of hip adductors- The exercise will be done in two sets of 10 repetitions for the legs in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 5.Heel raising - The exercise will be done in two sets of 10 repetitions for the legs in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 6. Standing on one leg-The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 7. Step up-The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 8. Leg cross-The patient is asked to sit on the chair and put one leg on the other, then extend the back leg; the exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 9.Sit to stand- The patient is asked to sit on the chair and get up while the hands on the chest and sit back on the chair. The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 10. The resisted exercise of the quadriceps femoris- After determining the proper weight, the exercise will be done in a set with 10 repetitions and the duration of holding it will be 5 seconds. In the second week, it will be done in two sets of 10 repetitions, and in the last two weeks, it will increase to three sets. 11. Reverse Straight legs raising (SLR)-The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. To do this exercise, the patient is asked to lie prone and then do SLR. 12. Sit to stand with the hip abduction-The patient is asked to sit on the chair and get up while the hands on the chest and the hips are abducted as wide as shoulder and sit back on the chair. The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 13. Standing Hip Abduction- The patient is asked to stand next to a chair while taking a chair with one of the hands, lifting one of the legs, and doing the hip abduction. The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 14. Standing Hip Adduction- The patient is asked to stand next to a chair while taking a chair with one of the hands, lifting one of the legs, and doing the hip adduction. The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three. 15. Standing Leg Curl- The patient is asked to stand next to a chair while taking a chair with one of the hands, lifting one of the legs, and doing the knee flexion. The exercise will be done in two sets of 10 repetitions for each leg in the first two weeks with a 5-second hold. In the second two weeks, the exercise sets will be increased to three.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Dr Sahar Kavand

Street address

Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan Ave.

City

Tehran

Province

Tehran

Postal code

14455613131

Phone

+98 21 6435 2446

Fax

+98 21 6651 7309

Email

sahar_kawand@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Azar Moezy
Street address
Iran University of Medical Sciences, Hemat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
azarmoezy@yahoo.com
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
10
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
Sahar Kavand
Position
Sport Medicine Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan .
City
Tehran
Province
Tehran
Postal code
14455613131
Phone
+98 21 6435 2446
Fax
+98 21 6651 7309
Email
sahar_kawand@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Azar Moezy
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports Physical Therapy
Street address
Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan Ave.
City
Tehran
Province
Tehran
Postal code
14455613131
Phone
+98 21 6435 2446
Fax
+98 21 6651 7309
Email
moezy.a@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Azar Moezy
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports Physical Therapy
Street address
Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan Ave,
City
Tehran
Province
Tehran
Postal code
14455613131

Phone
+98 21 6435 2446
Fax
+98 21 6651 7309
Email
moezy.a@iums.ac.ir

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 information, such as information on the main outcome or the like, 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
Researchers and specialists working in universities and health centers
Under which criteria data/document could be used
Analysis on the data delivered 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