Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of three different types of aerobic exercise program (lower body with and without weight bearing and upper body) on the outcomes of pain and function in knee osteoarthritis patients

Protocol summary

Summary

The aim of the study was to compare the effects of aerobic exercise program (with or without weight-bearing lower limb upper organs) in patients with knee osteoarthritis in pain and function outcomes.It is a randomized, single-center and single-blind (blinding for data analyzing group) study.The study population are patients with knee osteoarthritis, referring to Tehran University Sports Medicine Clinic in 2014-2015. People over 40 years with knee osteoarthritis confirmed according to the American College of Rheumatology diagnostic criteria, that radiologically categorized in grade 2 or 3 and are overweight or normal weighted are invited to the study. exclusion criteria are: patients with rheumatoid arthritis, knee or hip replacement surgery or any surgical procedure on lower limbs during the last 6 months, intra-articular corticosteroid injection at 6 months, and PRP gel in the previous year. Participants are allocated into three groups: A, B, C.They fill KOOS questionnaire and visual analog scale to assess pain and function tests before and after the intervention. Also the 6MWT, Timed up and go test and 30 second chair stand test in these patients are studied. Patients will do aerobic exercises with treadmill in Group A, cycle ergometer in group B and arm ergometer in group C .All three groups received non-weight bearing lower limb resistance training. They will do supervised center based exercises for 12 sessions. Finally, all three groups will be compared according to the changes of two outcome questionnaires and functional tests in terms of pain relief and increased performance will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507028117N4**

Registration date: **2015-10-13, 1394/07/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-13, 1394/07/21

Registrant information

Name

Farzin Halabchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research of Tehran University of Medical Sciences

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2016-03-01, 1394/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three different types of aerobic exercise program (lower body with and without weight bearing

and upper body) on the outcomes of pain and function in knee osteoarthritis patients

Public title
Comparison of three different types of aerobic exercise program (lower body with and without weight bearing and upper body) on the outcomes of pain and function in knee osteoarthritis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: People over 40 years old referred to sports medicine clinic at Tehran University that have the criteria for the diagnosis of osteoarthritis of the knee by the American College of Rheumatology and who have grade 2 or 3 osteoarthritis by defined radiological criteria according to Kellgren and Lawrence system and are overweight or have a normal body mass index. exclusion criteria: Patients with rheumatoid arthritis, knee or hip joint replacement surgery or any surgical procedure involving the lower extremities during the last 6 months, intra-articular corticosteroid injection at 6 months, and PRP gel in a years. use of oral corticosteroids or in last 4 weeks and physical disorders that prevent a person from doing exercise.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University Of Medical Sciences
Street address
Floor 5, Central building, Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2015-06-13, 1394/03/23
Ethics committee reference number
ir.tums.rec.1394.93-04-30-27160-151995

Health conditions studied

1

Description of health condition studied
Knee Osteoartritis
ICD-10 code
M17
ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
Pain
Timepoint
First, weeks 4 and 8
Method of measurement
Visual Analog Scale Questionnaire

2

Description
Function
Timepoint
First, weeks 4 and 8
Method of measurement
KOOS Questionnaire

Secondary outcomes

1

Description
Function
Timepoint
Beginning and end of the study
Method of measurement
6 Minute Walk test

2

Description
Function
Timepoint
Beginning and end of the study
Method of measurement
Timed up and go test

3

Description
Function

Timepoint
Beginning and end of the study
Method of measurement
30 second chair stand test

Intervention groups

1

Description
Resistance exercise for lower limb and Weight-bearing aerobic exercise of lower limb (treadmill) for 20 minutes at the borg 11_13
Category
Rehabilitation

2

Description
Resistance exercise for lower limb and Non-weight bearing aerobic exercise of lower limbs (cycling) for 20 minutes at the borg 11_13
Category
Rehabilitation

3

Description
Resistance exercise for lower limb and Aerobic exercises of upper limb (arm ergometry) for 20 minutes at Borg 11_13
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports Medicine Clinic in Imam Khomeini Hospital
Full name of responsible person
Sanaz Kabiri
Street address
Imam Khomeini Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research of Tehran University of Medical Sciences
Full name of responsible person
Khalilpour
Street address
Floor 5, Deputy of research, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty