

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 21 6119 2282

Email address

fhalabchi@tums.ac.ir

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 Osteoarthritis

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

Imam Khomeini Hospital

Full name of responsible person

Sanaz Kabiri

Position

Medical Doctor

Other areas of specialty/work

Street address

Imam Khomeini Hospital

City

Tehran

Postal code

Phone

+98 21 6119 2282

Fax

Email

Dr.sanzkabiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farzin Halabchi

Position

Associate Professor

Other areas of specialty/work

Street address

Sports and Exercise Medicine Ward, Imam Khomeini Hospital

City

Tehran

Postal code

Phone

+98 21 6119 2282

Fax
Email Fhalabchi@tums.ac.ir
Web page address

+98 21 6119 2282
Fax
Email dr.sanzkabiri@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sanaz Kabiri
Position
Medical Doctor
Other areas of specialty/work
Street address
Sports and Exercise Medicine Ward, Imam Khomeini
Hospital
City
Tehran
Postal code
Phone

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