

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Immediate Effect of Supplementary Cycle Ergometry and Treadmill Walking Exercise with Conventional Physical therapy on the Pain and Function in Patients with Moderate Knee Osteoarthritis

Protocol summary

Summary

This study wants to compare the effects of cycle ergometry and treadmill walking with conventional physical therapy. Participants with one or both knee pain on most days of the previous month occurring during weight-bearing activities and demonstrated radiographic changes; K-L grades of 2; At least 90 degree of knee range of motion; Age between 40-70 years and stable baseline blood pressure according to the American College of Sports Medicine guidelines for exercise will be included in the study. Participants with severe patellofemoral pain and cardiovascular disease and participants that be unable to walk on a treadmill will be excluded from the study. 30 participants with moderate knee OA will be divided to three subgroups include treadmill training group, cycle ergometer group and control group. Subjects will start attending Musculoskeletal Research Center, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences three times a week, for 10 sessions. The conventional physical therapy will take 40 minutes and treadmill training or cycle ergometer will take 17 minutes separately.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013120888N1**
Registration date: **2015-11-27, 1394/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

Zahra Sadat Rezaeian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice Chancellor of Research and Technology

Expected recruitment start date

2015-02-02, 1393/11/13

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Immediate Effect of Supplementary Cycle Ergometry and Treadmill Walking Exercise with Conventional Physical therapy on the Pain and Function in Patients with Moderate Knee Osteoarthritis

Public title

Comparison of the Immediate Effect of Supplementary Cycle Ergometry and Treadmill Walking Exercise with Conventional Physical therapy on the Pain and Function in Patients with Moderate Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: One or both knee pain on most days of the previous month occurring during weight-bearing activities and demonstrated radiographic changes; Patients with K-L grades of 2; At least 90 degree of knee range of motion; Age between 40-70 years; Stable baseline blood pressure according to the American College of Sports Medicine guidelines for exercise
Exclusion criteria: Serious medical conditions for which exercise will be contraindicated; Severe patellofemoral pain that will not allow participation in the stationary cycling regimen; Be unable to walk on a treadmill without an assistive device; Any cardiovascular disease as uncontrolled hypertension or unstable angina or neurological disorder (i.e. stroke, Parkinson's, etc.) that can affect patient gait in various forms; Presence of clinical symptoms of OA in hip, ankle or foot; Any significant foot disease that cause change in gait

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Isfahan University of Medical Sciences, Ethics Committee

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

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Isfahan

Postal code

81745-164

Approval date

2015-02-01, 1393/11/12

Ethics committee reference number

193079

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

Primary outcomes

1

Description

Pain

Timepoint

A day before starting the study and a day after the last exercise session

Method of measurement

VAS

2

Description

Function

Timepoint

A day before starting the study and a day after the last exercise session

Method of measurement

Koos, TUG, 6 min Walking Test

Secondary outcomes

1

Description

Cardovascular Fitness

Timepoint

A day before starting the study and a day after the last exercise session

Method of measurement

Bruce test

Intervention groups

1

Description

a. Tests and control groups will undergo a conventional physical therapy program of three sessions a week for ten sessions. Each session will take 40 minutes. Conventional physical therapy includes: 1. Acupuncture TENS (low rate): 2-10 HZ, 200-300 microsecond, 20-30 minutes, four electrodes over the superior and inferior medial and lateral poles of the

patella 2.Hot moist pack for 20 minute 3.Ultrasound: 1 MHz, 1.5-2 W, 5 minutes, continuous (1-2 minute per 1 cm2) It will cover the antero-medial and antro-lateral aspects of the knee around the patella 4.Quadriceps setting 5.VMO setting 6.Education

Category

Rehabilitation

2

Description

b.Intervention Group 1: Supplementary Cycle ergometer program: 1. One minutes pedaling: workload=0, self-selected speed of pedaling (RPM) [Warm-Up period] 2. Five minutes pedaling: RPM=50-60, gradual increase in workload to reach threshold heart rate at the end of 5 minute 3. Ten minutes pedaling: RPM=50-60, controlling the workload to preserve participant's heart rate at threshold heart rate 4.One minute pedaling: workload=0 and self-selected RPM [Active Recovery] 5.Five minutes rest at sitting position [Passive Recovery]

Category

Rehabilitation

3

Description

c.Intervention Group 2: Supplementary Treadmill program: Test group will take part in a 17-minute exercise program on treadmill as presented below: 1.One minutes walking with self-selected velocity [Warm-Up period] 2.Five minutes walking: gradual increase in velocity to reach threshold heart rate at the end of 5 minute. 3.Ten minutes walking with controlling velocity to preserve participant's heart rate at threshold heart rate 4.One minute walking: self-selected velocity [Active Recovery] 5.Five minutes rest at sitting position [Passive Recovery]

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Research Center

Full name of responsible person

Dr. Zahra Sadat Rezaeian

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Hezar Jarib Aven. Isfahan University of Medical sciences, Faculty of Rehabilitation Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice Chancellor of Research and Technology

Full name of responsible person

Zahra Fallah

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Hejar Jrib Ave. Isfahan University of Medical Sciences, Clinical Council

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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

Isfahan University of Medical Sciences, Vice Chancellor of Research and Technology

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

Musculoskeletal Research Center, Department of Physical therapy, Faculty of Rehabilitation Sciences,

Full name of responsible person

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Position

PhD, Assistant Professor

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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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