

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5042

##### Email address

zrezaeian@rehab.mui.ac.ir

#### 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

##### City

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

Cardiovascular 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

##### Street address

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

##### City

Isfahan

## 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

#### Street address

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

#### City

Isfahan

#### 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

Dr. Zahra Sadat Rezaeian

#### Position

PhD, Assistant Professor

#### Other areas of specialty/work

#### Street address

Hezar JaribAve. Isfahan University of Medical Sicences, Faculty of Rehabilitation Sciences, Musculoskeletal Research Center, Department of Physical Therapy

#### City

Isfahan

#### Postal code

81745-164

#### Phone

00983137925012; 00983137925042

#### Fax

+98 31 3668 7270

#### Email

zrezaeian@yahoo.com

#### Web page address

<http://scholar.google.com/citations?user=FXzUASAAA&hl=en>

## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Dr. Zahra Sadat Rezaeian

**Position**

PhD, Assistant Professor

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

Hezar JaribAve. Isfahan University of Medical  
Sciences, Faculty of Rehabilitation Sciences,  
Musculoskeletal Research Center, Department of  
Physical Therapy

**City**

Isfahan

**Postal code**

81745-164

**Phone**

00983137925012; 00983137925042

**Fax**

+98 31 3668 7270

**Email**

zrezaeian@yahoo.com

**Web page address**

[http://scholar.google.com/citations?user=FXzUASAAA  
AAJ&hl=en](http://scholar.google.com/citations?user=FXzUASAAA<br/>AAJ&hl=en)

## Person responsible for updating data

### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Dr. Zahra Sadat Rezaeian

**Position**

PhD, Assistant Professor

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

Hezar JaribAve. Isfahan University of Medical  
Sciences, Faculty of Rehabilitation Sciences,  
Musculoskeletal Research Center, Department of  
Physical Therapy

**City**

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**Phone**

00983137925012; 00983137925042

**Fax**

+98 31 3668 7270

**Email**

zrezaeian@yahoo.com

**Web page address**

[http://scholar.google.com/citations?user=FXzUASAAA  
AAJ&hl=en](http://scholar.google.com/citations?user=FXzUASAAA<br/>AAJ&hl=en)

## 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*