

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of continues and intermittent physical therapy on amount of pain and function in subjects with moderate knee osteoarthritis (pilot randomized clinical trial)

Protocol summary

Study aim

Determination of the effect of continuous and intermittent physiotherapy on the pain and function of patients with knee osteoarthritis.

Design

A pilot randomized clinical trial community based, double-blind (participant and outcome assessor).

Settings and conduct

Alzahra Medical Center. Participant and examiner are blind in this.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate knee osteoarthritis who are above 40. Exclusion criteria: Other problems associated with knee pain and function.

Intervention groups

The intervention includes 10 physiotherapy sessions. All patients (both groups) in physiotherapy sessions will receive the usual physical modalities equally. The difference between two groups is in the treatments sessions interval. One group receives physiotherapy treatment during 10 sessions everyday and one group receives physiotherapy treatment during 10 sessions, three sessions a week (every other day).

Main outcome variables

Pain; function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171017036837N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5041

Email address

mirbod@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-22, 1397/05/31

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of continues and intermittent physical therapy on amount of pain and function in subjects with moderate knee osteoarthritis (pilot randomized clinical trial)

Public title

The effect of continues and every another day physical therapy on pain and function in subjects with knee osteoarthritis.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary knee osteoarthritis Having criteria of knee osteoarthritis according to American college of rheumatology Patients with grade 2 or 3 Kellgren-lawrence scale of moderate knee osteoarthritis Age more than 40 years Not being in the acute phase of the disease Able to write and read Men and women with moderate knee osteoarthritis Body mass index less than 35

Exclusion criteria:

Systemic rheumatoid arthritis Secondary knee osteoarthritis Active knee synovitis Severe knee trauma Surgery intervention on knee during 1 year ago Intra-articular injection of corticosteroids or hyaluronic acid for at least the last 6 months Performing a physiotherapy treatment in the last 3 months Taking of Non steroidal anti-inflammatory drug from a week before entering the study Musculoskeletal disorders in lower extremities Disorders in lumbopelvic and hip region Bilateral involvement of knees which one of them is grade 4 Kellgren-lawrence scale

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Tools used in randomization (throwing coin)

Blinding (investigator's opinion)

Double blinded

Blinding description

Treatments are done by the researcher and evaluations are done by another assessor. The assessor doesn't know about patients grouping. The patients don't know about their group and other groups. since the treatment component was exactly the same in both groups except the frequency of sessions. the participants knew that they will receive standard physical therapy to determine its effect in Iranian subjects. Both groups truly receive standard intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences.

Street address

Secretariat of the Ethics Committee, Room 209, Second Floor, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

81745-164

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1396.3.436

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

Pain

Timepoint

One day before the intervention and at the tenth session after the end of the treatment plan

Method of measurement

Visual Analogue Scale

2

Description

Function

Timepoint

One day before the intervention and at the tenth session after the end of the treatment plan

Method of measurement

Get up and go test

3

Description

Pain

Timepoint

One day before the intervention and at the tenth session

after the end of the treatment plan
Method of measurement
Knee injury and osteoarthritis outcome score

4

Description

Pain

Timepoint

One day before the intervention and at the tenth session
after the end of the treatment plan

Method of measurement

Intermittent and constant osteoarthritis pain

5

Description

Function

Timepoint

One day before the intervention and at the tenth session
after the end of the treatment plan

Method of measurement

Six minute walk test

6

Description

Function

Timepoint

One day before the intervention and at the tenth session
after the end of the treatment plan

Method of measurement

Knee injury and osteoarthritis outcome score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 times a week, for 10 sessions every
another day will be done. Conventional physiotherapy
treatment includes these: 1. Transcutaneous electrical
nerve stimulation(TENS): 10HZ, 250 microsecond, 20
minutes, four electrodes medial and lateral to the
superior and inferior poles of the patella 2. Hot moist
pack for 20 minute 3. Ultrasound: 1 MHz, 2 Watt, 5
minutes, continuous(1-2 minute per 10 cm2) with
circular motion covering medial, lateral and anterior
aspects of the target knee joint. 4. Quadriceps setting 5.
VMO setting

Category

Rehabilitation

2

Description

Control group: 6 times a week, for 10 sessions every day
will be done. Conventional physiotherapy treatment
includes these: 1. Transcutaneous electrical nerve

stimulation(TENS): 10HZ, 250 microsecond, 20 minutes,
four electrodes medial and lateral to the superior and
inferior poles of the patella 2. Hot moist pack for 20
minute 3. Ultrasound: 1 MHz, 2 Watt, 5 minutes,
continuous(1-2 minute per 10 cm2) with circular motion
covering medial, lateral and anterior aspects of the
target knee joint. 4. Quadriceps setting 5. VMO setting

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Center

Full name of responsible person

Sayed Mohsen Mirbod

Street address

Sofeh boulevard

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8174675731

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mirbod@rehab.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery of Research and Technology

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Vice Chancellery Of Research and Technology,Isfahan
University of Medical Sciences, Hezar Jerib Ave.

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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

Vice Chancellery of Research and Technology

Proportion provided by this source

100
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
Esfahan University of Medical Sciences
Full name of responsible person
Sayed Mohsen Mirbod
Position
Instructor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available