Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of routine physiotherapy and Pilates exercise on pain, function and quality of life in women with knee osteoarthritis

Protocol summary

Summary

The aim of this study is to compare the effects of routine physiotherapy with Pilates exercise on pain, function and quality of life in women with knee Osteoarthritis. In this study 20 women in the age range of 50 _70 years with knee Osteoarthritis will be selected by simple sampling and then randomly divided into control and intervention groups.Control group treated with 12 sessions of low-frequency TENS & hot pack for 20 minutes, continuous ultrasound for 5 minutes and exercise . Intervention group over 12 sessions treated with Pilates exercises . In this study, pain, function and quality of life of patients will be evaluated, respectively, by the VAS index , functional tests Timed Up and Go Test and 30 - second Chair Stand Test and SF _ 36 quality of life questionnaire, at the first session o and the last session of treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604041552N6**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Maryam Ebrahimian

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice- Chancellor for Research Affairs of Shiraz University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of routine physiotherapy and Pilates exercise on pain, function and quality of life in women with knee osteoarthritis

Public title

Comparison of the effects of routine physiotherapy and Pilates exercise on pain, function and quality of life in women with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with knee osteoarthritis , age range 50_70 years old; have a pain in the range of 30_70 mm based on the VAS, score 2 or 3 of standard Modified Altman. Exclusion criteria: have been experienced physiotherapy or exercise therapy in the past 6 months; history of joint tap or steroid injection in the last year; active inflammation of the knee; pain at the hip and ankle; history of fracture or dislocation of lower limbs; any deformities in the lower extremitiesl; osteoporosis

based on the criteria of T-Score (T≤ -2.5); history of systemic, immune system, cardiovascular diseases.

Age
From **50 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
In front of Felestin Street, Zand Avenue

City
Shiraz

Postal code
1433671348

Approval date
2016-03-06, 1394/12/16

Ethics committee reference number
IR.SUMS.REC.1394.214

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
pain

Timepoint
Before and after treatment sessions

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
function

Timepoint
Before and after treatment sessions

Method of measurement
timed up and go test and 30 second chair stand test

2

Description
quality of life

Timepoint
Before and after treatment sessions

Method of measurement
SF39 questionnaire

Intervention groups

1

Description
Control group treated with 12 (4 weeks ,3 sessions) sessions of low-frequency TENS & hot pack for 20 minutes, continuous ultrasound treatment for 5 minutes and exercise

Category
Rehabilitation

2

Description
Intervention group over 12 sessions (4 weeks ,3 sessions) treated with Pilates exercises

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation Sciences School of Shiraz University of Medical Sciences

Full name of responsible person
Mahsa Zahedi

Street address
Abiverdi No.1 St., Shahid Chamran Blvd.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor for Research Affirs of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th fioor of Central Building of Shiraz University of Medi cal Sciences,In front of Felestin Street, Zand Avenue

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Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice- Chancellor for Research Affirs of Shiraz 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

Rehabilitation Sciences School of Shiraz University of Medical Sciences

Full name of responsible person

Mahsa Zahedi

Position

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Other areas of specialty/work

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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