

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the effectiveness of electromagnetic therapy on improving the symptoms of second and third degree knee osteoarthritis

Protocol summary

Study aim

Determining the effectiveness of electromagnetism in the magnet device in improving pain and function of patients with second and third degree knee osteoarthritis.

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 60 patients. Random Allocation version 2 software will be used for randomization.

Settings and conduct

This randomized study, with equal randomization with a simple sequence, a single-blind clinical trial, controlled with drug therapy, a parallel group study, on patients with second and third degree OA referring to the physical medicine and rehabilitation clinic of the university Isfahan Medical Sciences. Blinding will be done by the method of 2 replacement blocks of sampling. Blinding will be done for the person who collects the data and the person who performs the data analysis. Due to the nature of the study, there is no possibility of blinding the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2nd and 3rd degree OA diagnosis, age ≥ 40 years, daily symptoms since 6 months ago, pain with VAS ≥ 3 criteria. Exclusion criteria: intra-articular drug administration, systemic treatment with corticosteroids, knee pain due to malignant pathology, autoimmune and inflammation, history of knee surgery, pregnancy, metal implant

Intervention groups

Group A: Drug treatment with 1 tablet of meloxicam 15 mg once a day for 18 days and exercise therapy 3 times a day for 18 days, each for 20 seconds and 3 times each time. The magnet device is turned off for The patient is placed. Group B: PEMF treatment in this group is performed in addition to drug treatment and exercise using a magnet device. The number of sessions is 8 sessions, 3 times a week. The time of each session is 30

minutes.

Main outcome variables

Reducing knee osteoarthritis symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231007059642N1**

Registration date: **2023-10-22, 1402/07/30**

Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Saeideh Safinataj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 347 5411

Email address

saeide.safi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of electromagnetic therapy on improving the symptoms of second and third degree knee osteoarthritis

Public title
Investigating the effect of electromagnetism in reducing knee osteoarthritis symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Primary diagnosis of grade 2 and 3 OA based on ACR criteria, including radiological evidence, clinical examination and history Age ≥ 40 years The presence of dry knee symptoms and frequent daily pain since 6 months ago Symptomatic illness from at least 6 months ago Presence of pain with VAS ≥ 3 criteria
Exclusion criteria:
Intra-articular drug administration in the last 6 months Systemic treatment with corticosteroids or physical therapy in the last 6 weeks Cartilaginous consumption in the last 6 weeks Back radicular pains Knee pain caused by malignant, autoimmune and inflammatory pathology or caused by knee deformities such as genu valgum and genu varum etc. Patients who have a history of knee surgery Lack of cooperation and difficulty in referring and following the intervention process pregnancy Metal implant like heart pacemaker

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method is used. Sampling will be done by the method of alternating blocks of 2 in such a way that we will have 10 blocks of 3 and each block will contain 3 letters from the letters A and B, including AAB-ABA-BBA-BAB and..... (two groups of 30 Each patient is randomly given a card, the cards are in sealed envelopes, and the technician takes the envelopes in order and delivers them to the patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
Random Allocation version 2 software will be used.

Sampling will be done by the method of 2 permutation blocks in such a way that we will have 10 blocks of 4 and each block contains 4 letters from letters A and B including AABB-ABAB-BBAA-BABA and..... (two groups of 40) one card for each patient randomly It is given that the cards are in sealed envelopes and the technician takes the envelopes in order and delivers them to the patients. Due to the nature of the study, it is not possible to blind the patients. The person who collects the data does not know whether the data belongs to group A or group B. The person who analyzes the data does not know whether he belongs to group A or group B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences, Faculty of Medicine

Street address

Unit 5, Hafez Building, 4th dead end on the right, 28 Yavar Alley, Barazandeh Street

City

Isfahan

Province

Isfahan

Postal code

8193967748

Approval date

2023-10-03, 1402/07/11

Ethics committee reference number

IR.MUI.MED.REC.1402.242

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Symptoms of knee osteoarthritis

Timepoint

before, immediately and 6 weeks and 3 months after the end of the treatment

Method of measurement

Visual Analogue Scale and Western Ontario and McMaster Universities Osteoarthritis Index scale

Secondary outcomes

1

Description

Average pain intensity

Timepoint

Before, immediately and 6 weeks and 3 months after the end of the treatment

Method of measurement

Visual Analogue Scale

2

Description

Physical performance

Timepoint

Before, immediately and 6 weeks and 3 months after the end of the treatment

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

3

Description

Joint dryness

Timepoint

Before, immediately and 6 weeks and 3 months after the end of the treatment

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

4

Description

Range of motion

Timepoint

Before, immediately and 6 weeks and 3 months after the end of the treatment

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

Intervention groups

1

Description

Intervention group: In this group, drug treatment with 1 tablet of meloxicam 15mg once a day for 18 days and exercise therapy 3 times a day for 18 days, each for 20 seconds and 3 times each time. Sports include the following: Stretching of quadriceps and calf muscle, strengthening of quadriceps and hamstring. In addition

to drug therapy and exercise, the group is performed using the magno 915G device, made in Iran, located in the physical medicine and rehabilitation department of Amin Hospital. The number of PEMF sessions is 8 sessions, 3 times a week. The patient is in a supine position. The back (SUPINE) is placed on the bed. Then the entire knee area will be placed under the electromagnet device. The total treatment time per session is 30 minutes.

Category

Treatment - Devices

2

Description

Control group: In this group, drug treatment with 1 tablet of meloxicam 15mg once a day for 18 days and exercise therapy 3 times a day for 18 days, each for 20 seconds and 3 times each time. Sports include the following: Stretching of quadriceps and calf muscle, strengthening of quadriceps and hamstring. In this group, the magnet device is turned off for the patient.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Saeideh Safinataj

Street address

Amin Medical Education Center, Sanbulistan Street, Sina Steet, Shahada Square

City

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholam Reza Askari

Street address

Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib Street

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8174673461
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askari@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Saeideh Safinataj
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Unit 5, Hafez Building, 4th dead end on the right, 28
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person

Saeideh Safinataj
Position
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Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
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deadend, Yavar 28 alley, Barazandeh street
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Person responsible for updating data

Contact
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Full name of responsible person
Saeideh Safinataj
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Unit 5, hafez building, Right side of the 4th
deadend, Yavar 28 alley, Barazandeh street
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saeide.safi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to
make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to
make this available
Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available