

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study and comparison of the Effect of TECAR Therapy and physiotherapy in the Symptoms and Functions of the Patients with Knee Osteoarthritis

Protocol summary

Study aim

Determining and comparing the effect of TECAR therapy and physiotherapy in improving the symptoms and performance of patients with knee osteoarthritis

Design

A randomized controlled, parallel-group, single-blinded, phase 3 clinical trial of 46 patients

Settings and conduct

The present study will be conducted in physical medicine and rehabilitation clinic of Amin Hospital of Isfahan University of Medical Sciences in 2023-2024. The patients are divided into two groups, A and B, performing classical physiotherapy intervention and TECAR therapy, respectively. Functional status is measured based on WOMAC questionnaire and pain intensity based on VAS questionnaire immediately after treatment, 1 month later and 3 months later. Comparisons in two groups are made based on primary variables with the help of independent t-tests or chi-score for quantitative and qualitative variables, respectively. All analyzes are performed at the 5% error level and with the help of SPSS24 software.

Participants/Inclusion and exclusion criteria

Diagnosis of knee osteoarthritis by physical therapist and grades 2 and 3 of knee osteoarthritis based on Kellgren-Lawrence radiological grading; age 40 to 80 years; duration of pain more than one month; VAS pain score of at least 3; informed written consent to participate in the study

Intervention groups

Group A receives standard physiotherapy treatment, which includes IR, TENS, HP. The number of physiotherapy sessions is 10 sessions every other day for 60 minutes in the physiotherapy center of Amin Hospital of Isfahan University of Medical Sciences. In group B, TECAR therapy is performed using the WINBACK device, made in France, in the physiotherapy department of Amin Hospital, and the number of sessions is 6 twice a week.

Main outcome variables

Functional status based on WOMAC questionnaire, pain intensity based on VAS questionnaire

General information

Reason for update

wrong entrance of Kellgren-Lawrence grades including criterion and number of patients

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043931N5**

Registration date: **2024-03-01, 1402/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2024-12-22, 1403/10/02**

Update count: **1**

Registration date

2024-03-01, 1402/12/11

Registrant information

Name

Shila Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 5139

Email address

shila_haghighat@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study and comparison of the Effect of TECAR Therapy and physiotherapy in the Symptoms and Functions of the Patients with Knee Osteoarthritis

Public title

Study and comparison of the Effect of TECAR Therapy and physiotherapy in the Symptoms and Functions of the Patients with Knee Osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of knee joint osteoarthritis by a physical therapist and selecting patients with moderate to severe knee osteoarthritis based on physical examination and grades 2 and 3 osteoarthritis based on the Kellgren-Lawrence radiographic grading. Duration of knee pain over 1 month VAS score of at least 3 Written informed consent for participation in study

Exclusion criteria:

Contraindications of TECAR device such as pregnancy, pacemaker, cancer, open wounds, skin lesions, skin sensitivity and lack of heat perception No written informed consent Hyaluronic acid injections during the past 6 months or steroid injection 6 weeks before entry

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who will included in the study, will be randomly assigned to one of the two intervention groups. The randomization method is to generate 23 random numbers from 1 to 46 by Excel software to be assigned to the first intervention group and then assigning the remaining 23 numbers to the second intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who analyses the data is someone other than the researcher and is kept blind and unaware of the interventional groups.

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

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2024-02-21, 1402/12/02

Ethics committee reference number

IR.MUI.MED.REC.1402.444

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Functional status based on WOMAC questionnaire

Timepoint

Immediately after treatment, 1 month later, 3 months later

Method of measurement

WOMAC questionnaire

2

Description

Pain level

Timepoint

Functional status based on WOMAC questionnaire

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, TECAR therapy is performed using the WINBACK device, made in France, in the physiotherapy department of Amin Hospital, and the number of sessions is 6 twice a week.

Category

Rehabilitation

2

Description

Control group: receive standard physiotherapy treatment, which includes IR, TENS, HP. The number of physiotherapy sessions is 10 sessions every other day for 60 minutes in the physiotherapy center of Amin Hospital of Isfahan University of Medical Sciences.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Clinic of Amin Hospital

Full name of responsible person

Dr. Shila Haghighat

Street address

Amin Hospital, Sonbolestan St., Ebnesina Ave., Shohada Sq.

City

Isfahan

Province

Isfahan

Postal code

8148653141

Phone

+98 31 3445 5051

Email

aminhospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Marjan Mortazavi

Street address

Medicine department, Isfahan university, Hezar Jarib St

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

research@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

Dr Shila Haghighat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Amin Hospital, Sobolestan St., Ebnesina Ave., Shohada Sq.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

shila_haghighat@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shila Haghighat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Amin Hospital, Sobolestan St., Ebnesina Ave.,
Shohada Sq.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

shila_haghighat@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shila Haghighat

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Physical therapy clinic, Amin Hospital, Sonbolestan
St., Ebnesina Ave. Shohada Sq.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

shila_haghighat@med.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying
individuals

When the data will become available and for how long

The access period starts from 2024

To whom data/document is available

anyone

Under which criteria data/document could be used

-

From where data/document is obtainable

Pooria Yeganeh Fard - 09178085110

What processes are involved for a request to access data/document

-

Comments