Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The evaluation of the efficacy of high-intensity laser therapy on knee osteoarthritis

Protocol summary

Study aim
Determining the effect of high-intensity laser therapy on knee osteoarthritis

Design
The randomized, single-blinded clinical trial, with parallel groups, Phase 3 on 50 patients

Settings and conduct
In this randomized single-blinded clinical trial study, 50 patients with osteoarthritis of the knee will be included in study and randomly divided into 2 groups. One group will receive standard routine treatment and the other group will receive high-intensity laser treatment. Then the degree of disability and pain intensity of patients will be compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients with osteoarthritis of the knee (Step 2 or 3 based on the Kellgren and Lawrence criteria), in the age category 40 to 70 years, and consent to participate in the study. Exclusion criteria included having rheumatic diseases, diabetes and systemic inflammatory diseases, bursite anserina, knee osteoarthritis with dominant lateral involvement of the knee, injection of hyaluronic acid and glucosamine compounds during the last 6 months, corticosteroid injections over the past six weeks, tumor malignancies and the presence of any contraindications for laser treatment.

Intervention groups
Control group: Patients in this group will be taught isometric exercises to strengthen the quadriceps muscles with repetitions three times a day, 10 times each time. Meloxicam 15 mg daily, one tablet daily for two weeks, and topical Rahamin ointment three times a day are applied topically to the affected knee. Intervention group: In this group, in addition to the treatments prescribed in the control group, patients will be treated with HILI with a high-intensity laser device (model LUMIX C.P.S 6 watts made in Italy). The course will include 6 sessions of treatment three times a week for two weeks using a powerful laser.

Main outcome variables
Disability; Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220214054022N1**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**
Update count: **0**

Registration date
2022-04-18, 1401/01/29

Registrant information

Name
Mozhgan Aghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
maghaei@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-19, 1401/01/30

Expected recruitment end date
2023-02-19, 1401/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the efficacy of high-intensity laser therapy on knee osteoarthritis

Public title

The effect of high-intensity laser therapy on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with knee osteoarthritis (stage 2 or 3) Age category 40 to 70 years Satisfaction to participate in the study

Exclusion criteria:

Having rheumatic diseases, diabetes and systemic inflammatory diseases bursite anserina Knee osteoarthritis with predominant lateral involvement of the knee Injection of hyaluronic acid and glucosamine compounds during the last 6 months Corticosteroid injections over the past six weeks6 Having tumor malignancies Existence of any contraindications for laser treatment

Age

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

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The method is permuted block randomization. In this way, first using online software (sealed envelope), a sequence of random numbers will be created and by the same software, the generated numbers will be divided into 5 blocks of 10. Which is an equal number in each block will be 5 items from the intervention group and 5 items from the control group. So by doing each block, 5 patients (equally) will be assigned to each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to high-intensity laser therapy in one group, the Care provider is aware of the type of intervention in each of the two groups. But the patient is not aware of the different nature of the intervention in the two groups. In addition to the Outcome assessor, the statistical analyst will have no information about the type of intervention in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-02-13, 1400/11/24

Ethics committee reference number

IR.MUI.MED.REC.1400.799

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

Pain

Timepoint

Before treatment, immediately and three months after the last treatment session

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Disability

Timepoint

Before treatment, immediately and three months after the last treatment session

Method of measurement

the Western Ontario and McMaster University Osteoarthritis Index (WOMAC)

Intervention groups

1

Description

Control group: Patients in this group will be taught isometric exercises to strengthen the quadriceps muscle with repetitions three times a day, 10 times each time. Meloxicam 15 mg daily, one tablet daily for two weeks, and topical ointment Rahamin three times a day topically applied on the affected knee.

Category

N/A

2

Description

Intervention group: In this group, in addition to the treatments prescribed in the control group, patients will be treated with high-intensity laser irradiation with a high-intensity laser device (model LUMIX C.P.S 6 watts made in Italy). The course will include 6 sessions of treatment three times a week for two weeks using a powerful laser.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Parisa Taheri

Street address

Department of Physical Medicine and Rehabilitation, Al-Zahra Hospital, Hezar Jarib Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Parisa Taheri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Physical Medicine

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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