

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of Interstitial Laser Therapy in Improving Pain and Function in Osteoarthritis

#### Protocol summary

##### Study aim

Determining and comparing the therapeutic effects of high-power and interstitial lasers in improving pain and function in patients with osteoarthritis.

##### Design

A randomized, parallel clinical trial study in 2025 on 60 patients with knee osteoarthritis who were randomly assigned to one of two intervention groups.

##### Settings and conduct

In this study, patients with knee osteoarthritis who refer to the physical medicine clinics of Isfahan University of Medical Sciences will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using a randomized block method.

##### Participants/Inclusion and exclusion criteria

Patients with inclusion criteria: 1) osteoarthritis according to the American College of Rheumatology criteria 2) osteoarthritis grade I or II according to the Kellgren-Lawrence grade 3) Total score of at least 25 on the (WOMAC) 4) Pain  $\geq 4$  on the (VAS) 5) Willingness to participate to the treatment plan

##### Intervention groups

group1: in the high-power laser group were treated in the following way: high-power laser was performed in 4 sessions, first 2 sessions per week and then one session per week with a diode laser with a power of 1 watt, a wavelength of 808 nanometers, an energy density of 60 J/CM<sup>2</sup>, at 5 points on the knee with a total of 300 joules. group2: intratissue laser group, under sterile conditions, an 18 gauge Winset needle is inserted from the medial side of the knee joint. Then, a sterile optical fiber specifically for intratissue lasers is inserted into the tissue through the needle. The optical fiber is connected to a low-power diode laser with a power of 0.25 watts wavelengths of 670, 808, and 450 nm. With a total energy of 15 joules (each wavelength 5 joules), laser sessions are performed in 4 sessions: 2 sessions in the first week and then one session per week.

##### Main outcome variables

pain, function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231203060255N4**

Registration date: **2025-07-18, 1404/04/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-07-18, 1404/04/27**

Update count: **0**

##### Registration date

2025-07-18, 1404/04/27

##### Registrant information

##### Name

Fateme Hoseinzade

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3233 0973

##### Email address

fatemehoseinzade@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-07-11, 1404/04/20

##### Expected recruitment end date

2025-09-23, 1404/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the effect of Interstitial Laser Therapy in Improving Pain and Function in Osteoarthritis

### Public title

Investigating the effect of Interstitial Laser Therapy in Improving Pain and Function in Osteoarthritis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Knee osteoarthritis according to the American College of Rheumatology criteria Knee osteoarthritis grade I or II according to the Kellgren-Lawrence grading Total score of at least 25 on the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire(knee pain severity  $\geq 4$  on the visual analog scale (VAS) in the past 3 months Willingness to participate and adhere to the treatment plan.

#### Exclusion criteria:

Unwillingness to participate in the study Grade 3 knee osteoarthritis Systemic diseases including uncontrolled diabetes, rheumatoid arthritis, cancer, etc. Skin lesions at the site of laser treatment, including wounds and any skin rash

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

How to select the sample: random sampling is done by consecutive non-probability sampling, and the number of samples is based on the calculation formula and the number of 30 people in each group, a total of 60 people (n=30). and random allocation ,the samples included in the study are allocated to 2 groups using SPSS software. In this way, 30 random numbers from 1 to 60 are created by Excel software, which are assigned to the first intervention group, and then the remaining 30 numbers are assigned to the second group

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Research Ethics Committee of the "Alzahra Research Centers"

##### Street address

Hazar 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

2025-05-06, 1404/02/16

#### Ethics committee reference number

IR.MUI.MED.REC.1404.066

## 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 the intervention and after the end of the intervention, one month after the intervention and three months after the end of the intervention

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Patient function

#### Timepoint

Before the intervention and after the end of the intervention, one month after the intervention and three months after the end of the intervention

#### Method of measurement

(WOMAC) Western Ontario McMaster Universities Osteoarthritis Index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in the high-power laser group were treated in the following way: high-power laser was performed in 4 sessions, first 2 sessions per week and then one session per week with a diode laser by fisoiline company made in Italy with a power of 1 watt, a wavelength of 808 nanometers, an energy density of 60 J/CM<sup>2</sup>, at 5 points on the knee with a total of 300 joules

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: Intervention group 2: In the intratissue laser group, it is performed in the following way: under sterile conditions, an 18 gauge Winset needle is inserted from the medial side of the knee joint. Then, a sterile optical fiber specifically for intratissue lasers is inserted into the tissue through the needle. The optical fiber is connected to a low-power diode laser with a power of 0.25 watts weber company made in Germany and wavelengths of 670, 808, and 450 nm. With a total energy of 15 joules (each wavelength 5 joules), laser sessions are performed in 4 sessions: 2 sessions in the first week and then one session per week.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amin hospital

##### Full name of responsible person

Fateme Hoseinzade

##### Street address

Shahada Square, Ibn Sina St., Sanbulistan St., Amin Medical Education Center

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8148653141

##### Phone

+98 31 3112 2020

##### Email

fatemehoseinzade98@gamil.com

##### Web page address

<https://amin.mui.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Gholamreza Asgari

##### Street address

Building No. 4, Hazar Jarib Street, Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### Email

askari@mui.ac.ir

##### Web page address

<https://research.mui.ac.ir/fa>

#### 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

fateme hoseinzade

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

##### Street address

Hazar Jarib St., Isfahan University of Medical Sciences

##### City

isfahan

##### Province

Isfahan

##### Postal code

91746734461

##### Phone

+98 31 3668 0048

**Email**

fatemehoseinzade98@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fateme Hoseinzade

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

91746734461

**Phone**

+98 31 3668 0048

**Email**

Fatemehoseinzade98@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fateme Hoseinzade

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

Fatemehoseinzade98@gamil.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