

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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, bursitis 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 HILL 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**  
Isfahan  
**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.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3620 2020

##### Email

Prs\_taheri@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Mansour Siavash Dastjerdi

##### Street address

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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8597

##### Email

dean@med.mui.ac.ir

#### 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

##### Street address

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

##### City

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##### Province

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##### Postal code

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##### Phone

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**Email**

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**Person responsible for scientific 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**

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**Phone**

+98 31 3620 2020

**Email**

Prs\_taheri@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Mozghan Aghaei

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

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

**City**

Isfahan

**Province**

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**Postal code**

8174673461

**Phone**

+98 31 3620 2020

**Email**

maghaei@resident.mui.ac.ir

**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