

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of low and high power laser therapy on pain, disability and range of motion in patients with knee osteoarthritis: a comparative clinical trial study

#### Protocol summary

##### Summary

The main aim of this study is comparison between long terms and immediately effects of high and low power laser therapy on knee osteoarthritis symptoms. This study is a clinical trial that will be done on 50 patients with knee osteoarthritis who referred to physiotherapy clinics of Semnan University of Medical Sciences by physician. Volunteers informed about the experimental procedure and purpose of this study. Main inclusion criteria are osteoarthritis of the knee and main exclusion criteria include factors that affect knee pain. Subsequently, their written informed consent is obtained. The patients were randomly assigned to three groups: The patients were randomly assigned to three groups: 1- standard treatment with placebo laser 2-standard treatment with low power laser 3-standard treatment with high power laser groups. In the low power laser group, a Gal-AL-AS diode laser device with a power output of 30 MW and a wavelength of 830 NM and in the high power laser group, a Gal-AL-AS diode laser device with a power output of 3.2 W and a wavelength of 910 NM will be used. In the placebo group, the same points and the similar duration will be applied while turned off the laser device. Standard treatment is Ultrasound, TENS current. Hot pack, Straight Leg Raising in supine position. They will be treated for ten session, 5 times weekly and in period of two weeks. Pain, disability, functional ability and ROM will be investigated before, immediately and 6 weeks after study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502224549N8**

Registration date: **2015-05-19, 1394/02/29**

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

Last update:

Update count: **0**

##### Registration date

2015-05-19, 1394/02/29

##### Registrant information

###### Name

Elham Fatemy

###### Name of organization / entity

Semnan University Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1335 4180

###### Email address

fatemy@sem-ums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Semnan University of Medical Sciences

##### Expected recruitment start date

2015-04-19, 1394/01/30

##### Expected recruitment end date

2015-07-21, 1394/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of low and high power laser therapy on pain, disability and range of motion in patients with knee osteoarthritis: a comparative clinical trial study

##### Public title

The effect of laser therapy on knee Osteoarthritis treatment

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1-Unconscious chronic unilateral knee Osteoarthritis that has an intensity of 1-3 on the radio graphs. 2- Having local pain in the knee region that was greater than 4 with regard to VAS. 3- Earn a minimum score of 25 regard to the WOMAC scale. Exclusion criteria: 1- History of knee fracture, Knee tendons and ligaments injury, meniscus or knee surgery. 2- Rheumatoid arthritis. 3- Risk of bleeding. 4- Musculoskeletal disorders of hip and ankle. 5- Central and peripheral neuropathy. 6- History of physiotherapy in the last 6 months. 7- History of corticosteroid articular injection in the last 6 months. 8- Oral anti coagulation medication. 9- Unconscious patients. 10- Neoplasm. 11- Deep vein thrombosis. 12- Pacemaker. 13- Neurological deficits. 14- Severe Obesity.

## Age

From **45 years** old to **65 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Sampling is convenience and the volunteers are randomly allocated to three groups by lottery.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

Kilometer 5, Damghan Road

##### City

Semnan

##### Postal code

##### Approval date

2015-03-17, 1393/12/26

## Ethics committee reference number

584671.93

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis of the knee joint

#### ICD-10 code

M19.0

#### ICD-10 code description

Primary Osteoarthritis of other joints

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

Before, immediately and 6 weeks after intervention

#### Method of measurement

Visual Analogue Scale(VAS) Questionnaire

### 2

#### Description

Range of motion

#### Timepoint

Before, immediately and 6 weeks after intervention

#### Method of measurement

Via the goniometry that show the range of motion with degree.

### 3

#### Description

Disability

#### Timepoint

Before, immediately and 6 weeks after intervention

#### Method of measurement

WOMAC Western Ontario Mac Master(WOMAC) Questionnaire

### 4

#### Description

Functional ability

#### Timepoint

Before, immediately and 6 weeks after intervention

#### Method of measurement

Via the "Two minutes walk test " that determinate the distance walked with Meter.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the low power laser group the treatment that applied is 1 MHZ continuous mode Ultrasound with duration of 5 MIN and intensity of 1 W.CM2, TENS current with frequency of 100 HZ and pulse duration of 0.05 MS and the time of treatment of 15 MIN. Hot pack, SLR in supine position and Gal-AL-AS diode laser device with a power output of 30 MW and a wavelength of 830 NM will be used.

#### Category

Rehabilitation

### 2

#### Description

In the placebo laser group the treatment that applied is 1 MHZ continuous mode Ultrasound with duration of 5 MIN and intensity of 1 W.CM2, TENS current with frequency of 100 HZ and pulse duration of 0.05 MS and the time of treatment of 15 MIN. Hot pack, SLR in supine position and A same laser device will be used while turned off the laser device.

#### Category

Rehabilitation

### 3

#### Description

In the high power laser group the treatment that applied is 1 MHZ continuous mode Ultrasound with duration of 5 MIN and intensity of 1 W.CM2, TENS current with frequency of 100 HZ and pulse duration of 0.05 MS and the time of treatment of 15 min. Hot pack, SLR in supine position and A Gal-AL-AS diode laser device with a power output of 3.2 W and a wavelength of 910 NM will be used.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The Rehabilitation Center of Tabatabaee

##### Full name of responsible person

Elham Fatemy

##### Street address

Mashahir Square, in front of Helal Ahmar

##### City

Semnan

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

#### Full name of responsible person

Ali Rashidipour

#### Street address

Kilometer 5, Damghan Road

#### City

Semnan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Semnan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Elham Fatemy

##### Position

MS.c-Instructor

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

#### Contact

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*