# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Efficacy of low level laser on knee osteoarthritis treatment

## Protocol summary

**Summary**
The main aim of this study was to investigate the Low Level Lasers (LLL) efficacy in alleviating the symptoms associated with knee OA. This is a single blind clinical trial in which that 36 adults patients (aged 45-75 years old) with knee OA participated in this study. The patients were randomly assigned to receive active laser with standard treatment or placebo laser with standard treatment. In the intervention group, a Gal-Al-As diode laser device with a power output of 30 mW and a wavelength of 830 nm was used that the probe was applied in grid cycloid form in ten points on the medial and lateral joint line. In the placebo group, the same points and the similar duration was applied while turned off the laser device. The standard treatment was 1- Ultrasound 2- TENS current 3-Infra Red radiation 4- Straight Leg Raising in supine position. They were treated for ten session¸ 5 times weekly and in period of two weeks. Pain at rest, duration of morning stiffness, active range of knee flexion, and the quality of life with WOMAC index were assessed before and after the intervention.

## General information

**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT201010104549N2**
Registration date: **2010-10-24, 1389/08/02**
Registration timing: **retrospective**

Last update:
Update count: **0**
**Registration date**
2010-10-24, 1389/08/02

**Registrant information**
**Name**
Elham Fatemy
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Semnan University Medical Sciences
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**Recruitment status**
**Recruitment complete**
**Funding source**
Semnan University of Medical Sciences

**Expected recruitment start date**
2009-09-29, 1388/07/07
**Expected recruitment end date**
2010-01-26, 1388/11/06
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Efficacy of low level laser on knee osteoarthritis treatment

**Public title**
Efficacy of laser on knee Arthrosis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: Presence of Idiopathic unilateral knee OA, age 45-75 years, ability of walking, having local pain in the knee region that was greater than 5 with regard to VAS and greater than 48 with regard to the WOMAC scale, Exclusion criteria: having other disorders of knee, affecting hip and ankle joints, lumbar spine pathology, presence of intra-articular effusion, past history of physical therapy or injection into the joint space since 6 months ago, presence of any infection, active bleeding, past history of knee joint surgery

**Age**
From **45 years** old to **75 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **36**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Semnan University of Medical Sciences
**Street address**
Kilometer 5, Damghan Road
**City**
Semnan
**Postal code**
3513138111
**Approval date**
empty
**Ethics committee reference number**
9 /12901/ Ī

## Health conditions studied

### 1

**Description of health condition studied**
Osteoarthritis of the knee joint
**ICD-10 code**
M19.0
**ICD-10 code description**
Primary arthrosis of other joints

## Primary outcomes

### 1

**Description**
pain at rest
**Timepoint**
before first session and after tenth session
**Method of measurement**
on basis of VAS

### 2

**Description**
duration of morning stiffness
**Timepoint**
in the onset of first session and after the final session
**Method of measurement**
recording of the duration via the patients at minute and quastion of their

### 3

**Description**
Active Kee flexion Range of Motion
**Timepoint**
onset of first session and after the tenth session
**Method of measurement**
via the goniometer by therapist

### 4

**Description**
Quality of life
**Timepoint**
onset of first session and after the tenth session
**Method of measurement**
via questioning of patients on the basis of WOMAC index

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The standard treatment that applied to the each of two groups was 1-A 1 MHz continous mode Ultrasound with applicator cross section of 0/8 cm2 in medial and lateral aspect of joint line, duration of 5 min and intensity of 1 w/cm2 .2- TENS current with frequency of 100 Hz and pulse duration of 0/05 ms and the time of treatment of 15 min.3-Infra Red radiation with power of 250 watt and 45 cm distance from the knee4- SLR in supine position, 30 fold. In the control group A Gal-Al-As diode laser device with a power output of 30 mW and a wavelength of 830 nm was used. Probe of laser applied in pattern of cycloid grid in 5 points in antero-medial side and 5 points in the antero-lateral side of knee joint line. In Each session 3 j/per point and a total dosage of 30j/cm2 were applied. In the placebo group, the same points and the similar duration was applied while turned off the laser device.
**Category**
Rehabilitation

**2**

**Description**
The standard treatment that applied for the control group was 1-A 1 MHz continous mode Ultrasound with applicator cross section of 0/8 cm2 in medial and lateral aspect of joint line, duration of 5 min and intensity of 1 w/cm2 .2- TENS current with frequency of 100 Hz and pulse duration of 0/05 ms and the time of treatment of 15 min.3-Infra Red radiation with power of 250 watt and 45 cm distance from the knee 4- Straight Leg Raising in supine position, 30 fold. The same Gal-Al-As diode laser device was applied on the same points as the Active laser group while turned off the laser device. Probe of laser was applied in pattern of cycloid grid in 5 points in antero-medial side and 5 points in the antero-lateral side of knee joint line. The duration of treatment on each point was 30 second.

**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
The Rehabilitation Center of Tabatabaee

**Full name of responsible person**

**Street address**
Mashahir Square, in front of Helal Ahmar

**City**
Semnan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Semnan University of Medical Sciences

**Full name of responsible person**
Elham Fatemi

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Department of Physiotherapy, Rehabilitation Faculty, Semnan University of Medical Sciences

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Semnan

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
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

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## 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*