Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

Name of organization / entity

Semnan University Medical Sciences

Country

Iran (Islamic Republic of)

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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

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

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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

Contact

Name of organization / entity
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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