Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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

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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