Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparing the effect of Low Level Laser Therapy on Mechanical LBP(without radiculopathy) with Naproxen

Protocol summary

Summary

we designed this study to evaluate the effect of low level laser therapy in some other musculoskeletal disorders and importance of low back pain. Our study was a one side blind, randomized controlled trial. 40 subjects with low back pain entered the study. Patients were aged between 20-70 and their pain severity scale was 3-10 according to visual analogue scale of pain .They were randomly assigned in two groups: true laser and control (sham laser). Naproxen was prescribed with a free dose (250- 1000 mg/daily) in both groups. We evaluated patients' subjective pain, functional status (using Roland Morris disability questionnaire), spinal tenderness at the basic time, one and three months post- treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201711058146N28**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Laser Application Research Center in Medical Sciences - Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Low Level Laser Therapy on Mechanical LBP(without radiculopathy) with Naproxen

Public title

Comparing the effect of Low Level Laser Therapy on low back pain with Naproxen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being over the age of; A written consent form has been signed; VAS level is between 10-3; According to the expert's diagnosis, the cause of their lower back pain is mechanical and lack of radiculopathy; Their lower back pain is more than three months; Exclusion criteria: Patients requiring emergency surgery:Bladder symptoms such as bladder loss, bladder loss, incontinence, lack of Sense while passing urine, Stomach incontinence , Anesthetizing around the anus ; Pregnancy; Discontinuation of the drug prescribed in / out of the protocol for the administration of the drug; A history of serious gastrointestinal complications (perforation / bleeding) due to the use of various types of

NSAIDs; Being / detecting any type of cancer 6 patients with heart problems; Patients who have spinal cord stenosis;Radiculopathy (Pulmonary to subcutaneous pain); Sensory impairment; Muscle weakness; Patients who have taken rococtane over the past 3 months; Patients with asthma, allergic to aspirin or nasal polyps; Patients with severe depression and not being treated; Patients with psychosis;

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational committee of ethics in biomedical research Shahid Beheshti University of Medical Scie

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City
Tehran

Postal code

Approval date
2011-12-11, 1390/09/20

Ethics committee reference number
IR.SBMU.RETECH.REC.1390.109

Health conditions studied

1

Description of health condition studied
Mechanical LBP(without radiculopathy)

ICD-10 code
G54.1

ICD-10 code description
Lumbosacral plexus disorders

Primary outcomes

1

Description
The degree of disability patients

Timepoint
One month after the treatment and the end of the third month

Method of measurement
Ronald-Morris Questionnaire and Oswestry Standard

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For a period of one month, the lasers are powered by a 808nm diode laser device with a power supply of 160 mW, and the lumbar, trigger points, thunder points, and some acupuncture points will be exposed. Naproxen A dosage of 250-2000 mg per day is administered free of charge (ie, if appropriate), and the daily intake is recorded in a table.

Category
Treatment - Other

2

Description
Control group: One month is used in the laser. Naproxen is given at a dose of 1000-250 mg daily for free (ie, if necessary) intake and daily intake is recorded in a table

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Laser Application Research Center in Medical Sciences

Full name of responsible person
Dr.Leila Kholoosi

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City
Tehran

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,Shahid Beheshti 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
Laser Application Research Center in Medical Science

Full name of responsible person
Dr.Leila Kholoosi

Position
MD

Other areas of specialty/work

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Teharn

Postal code

Phone
+98 21 2274 9221

Fax

Email
Lilykh.md2537@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Laser Application Research Centre in Medical Sciences

Full name of responsible person
Dr.Darush Eliaspoor

Position
Physical medicine & rehabilitation specialist

Other areas of specialty/work

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Teharn

Postal code

Phone
+98 21 2274 9221

Fax

Email
d.eliaspour@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Laser Application Research Centre in Medical Sciences

Full name of responsible person
Dr.Leila Kholoosi

Position
MD

Other areas of specialty/work

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Tehran

Postal code

Phone
+98 21 2274 9221

Fax

Email
Lilykh.md2537@yahoo.com

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