

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of an 808 nm diode laser (160 mv) with Naproxen in reducing the pain in mechanical low back pain patients

Protocol summary

Study aim

Evaluation of the effect of 808 nm diode laser (160 mw) on Low back pain (LBP) compared to Naproxen

Design

A randomized, single blind, sham controlled clinical trial with a parallel group design of 40 patients

Settings and conduct

This study was conducted on 40 patients with mechanical low back pain in two groups, the intervention group and the control group. Subjects in both groups were prescribed naproxen per need. Patients in the intervention group received 12 sessions of laser therapy with a 808 nm diode laser. the control group attended 12 sessions of sham laser therapy. The device was the same, but it was off during treatment sessions. Patients' demographic characteristics, pain severity, and functional status were obtained and documented in a preliminary visit. At the end of the first and third months after the treatment and all the above-mentioned items were reassessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: LBP (low back pain) patients Exclusion criteria: radiculopathy

Intervention groups

The patients in the present study were randomly assigned to two groups. Each group consisted of 20 Patients. both groups were prescribed naproxen per need (up to 1000 mg daily). 1) The intervention (true laser) group received 12 sessions of laser therapy with the frequency of 3 sessions per week. Laser characteristics were as follows: diode laser, wavelength 808 nm, power 160 mW 2) The control (sham laser) group attended 12 sessions of sham laser therapy. The device was the same, but it was off during treatment sessions.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N32**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **retrospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

2012-02-20, 1390/12/01

Actual recruitment end date

2012-05-21, 1391/03/01

Trial completion date

2012-10-22, 1391/08/01

Scientific title

Comparison of the effectiveness of an 808 nm diode laser (160 mv) with Naproxen in reducing the pain in mechanical low back pain patients

Public title

comparison of the effect of a low level diode laser with Naproxen on low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

complaint of chronic mechanical low back pain (more than 3 months) pain severity : 3-10 according to the visual analogue scale of pain (VAS) at least 20 years old signing the written informed consent

Exclusion criteria:

Radiculopathy Subjects with a history of motor or sensory deficits Pregnancy NSAIDs-induced serious gastrointestinal problems such as bleeding/perforation a need to emergent/urgent surgery malignancy active gastric ulcers aspirin sensitivity Rheumatologic diseases undertreated severe depression

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization table was used. A series of numbers were selected. even numbers and odd numbers were allocated to the intervention group and control group respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients were randomly assigned to two groups, the intervention (true laser) and the control (sham laser).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2011-12-11, 1390/09/20

Ethics committee reference number

85248/1398/08/20 -1398/5

Health conditions studied

1

Description of health condition studied

Mechanical low back pain

ICD-10 code

M54.5

ICD-10 code description

low back pain

Primary outcomes

1

Description

pain severity (from 0 to 10) based on visual analogue scale

Timepoint

Evaluation of low back pain severity before intervention and at the end of the first and third months after the treatment

Method of measurement

visual analogue scale

2

Description

functional status

Timepoint

evaluation of the functional status before the intervention and at the end of the first and third months after the treatment

Method of measurement

Ronald-Morris disability questionnaire (RMDQ)

3

Description

Anterior and lateral flexion range of motion (ROM) of vertebral column in Cm

Timepoint

Before the intervention and at the end of the first and third months after the treatment

Method of measurement

Physical examination

4

Description

spinal tenderness

Timepoint

Before the intervention and at the end of the first and third months after the treatment

Method of measurement

Physical examination

Secondary outcomes

1

Description

patients' satisfaction with the treatment process

Timepoint

At the end of the first and third months after the treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Subjects took the protective instructions and were prescribed naproxen per need (up to 1000 mg daily). Patients received 12 sessions of laser therapy with the frequency of 3 sessions per week. Laser characteristics were as follows: Infrared laser GaAlAs, wavelength 808 nm, power 160 mW and penetration depth of 4 cm. We applied the laser to articular spaces of vertebral column (3 points on each disc, each one for 30 seconds, 4.5 J/cm² on each point), adjacent paravertebral points (1 point on each side, 30 seconds, 4.5 J/cm² on each point), pain radiating areas and tender points (at least 12 points, with the dosage of 4.5 J/cm²) and also pain-controlling acupuncture points (LI4, ST44, H7) with the dosage of 1.5 J/cm² (10 seconds on each point).

Category

Treatment - Other

2

Description

Control group: Subjects took the protective instructions and were prescribed naproxen per need (up to 1000 mg daily). Patients received 12 sessions of sham laser therapy with the frequency of 3 sessions per week as described in intervention group. The device was the same as the intervention group, but it was off during treatment sessions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Mohammad Reza Razaghi

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Shohadaye Tajrish Hospital, Tajrish, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohamadreza razaghi
Position
Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable