

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Compare between non steroid anti inflammatory drug and Different Frequency of pulse low level laser therapy in acute Low Back Pain

Protocol summary

Summary

Goal: this study done to compare between anti-inflammatory effects of two different frequency of pulse low level laser therapy with dose of 6 j/cm² and NSAID therapy in patients with acute LBP. Design: Double-blind, randomized, placebo-controlled study. Material & method: study performed in four groups of acute LBP with radiculopathy is associated with pain and disability; group A is treated with analgesic dose of NSAID and active pulse low level laser therapy with frequency of 10 Hz and dose of 6 j/cm², group with same doses of NSAID and active pulse low level laser therapy with same dose with frequency of 250 Hz; group C with placebo LLLT and same dose of NSAID and group D only NSAID therapy. LLLT with same dose but with two different frequency is applied behind the involved spine segments in six areas. Patients treated 3 times per week for a total 12 treatments with following parameters, wavelength of 810 nm and dose of 6 j/cm² with frequencies of 10 and 250 hz .outcome is pain intensity measured with visual analogue scale in lumbar and leg segments and ODI questionnaire of ADL. VAS measures before and after and with one week interval and ODI questionnaire before and after treatments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052213146N2**
Registration date: **2013-12-15, 1392/09/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-15, 1392/09/24

Registrant information

Name

Maryam Hayati

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare between non steroid anti inflammatory drug and Different Frequency of pulse low level laser therapy in acute Low Back Pain

Public title

Compare between pulse lasertherapy and none steroid antiinflammatory drug in acute low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: LBP less than3 months; age range between 30-60 years old; not pregnant; have not spinal surgery in recent years; have not systemic and

psychological disorders. Exclusion criteria: spondylosis; spinal stenosis; malignant inflammatory disorders; smoking and addiction.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar
bolverd

City

Qazvinq

Postal code

59811-34197

Approval date

2012-06-25, 1391/04/05

Ethics committee reference number

28/20/6035

Health conditions studied

1

Description of health condition studied

Acute low back pain

ICD-10 code

M51.2

ICD-10 code description

Other specified intervertebral disc displacement

Primary outcomes

1

Description

Pain

Timepoint

Before and after and weekly during treatment

Method of measurement

VAS scale

2

Description

Functional quality

Timepoint

Before and after

Method of measurement

ODI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

6 j/cm2 low level laser therapy with frequency of 10 hz
and NSAID therapy with analgesic dose

Category

Other

2

Description

placebo low level laser therapy and NSAID therapy with
analgesic dose

Category

Placebo

3

Description

6 j/cm2 low level laser therapy with frequency of 250 hz
and NSAID therapy with analgesic dose

Category

Treatment - Other

4

Description

NSAID therapy with analgesic dose s a control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical center of Qazvin University of Medical Sciences

Full name of responsible person

Dr Mahnaz Abbasi

Street address

Opposite of Mehregan hospital, Ferdosi avenue

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mahnaz Abbasi

Street address

Vice-chancellor for research, Qazvin University of Medical Sciences

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Hayati

Position

PhD candidate

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