Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of the effect of High intensity laser therapy (HILT) versus low intensity laser therapy (LILT) on pain and functional improvement of the patients with non-specific chronic low back pain

Protocol summary

Summary

Objectives: Chronic low back pain is one of the most prevalent musculoskeletal disorders which has been attempted for many years to prescribe more efficient treatment protocols. Based on the literature, there are evidences for the effect of laser therapy on reduction of the pain in the back area but the priority of any kind laser therapy on the treatment of the low back pain is unknown, especially when considering the same dose level. Higher price of the high intensity laser therapy and also higher safety level demands on application of this kind of laser compared with low intensity laser therapy, shows the necessity of further researches on this filed to evaluate the effect of both kind of laser therapy at the same dose level. Design: present research is a single blinded randomized clinical trial study.Setting and conduct: Thirty participants with chronic low back pain (aged 18-40 Ys) will participated in the study via convenience sampling method. Initial assessment will include pain level detection by visual analogue scale and functional level evaluation by Oswestry questionnaire. Participants will be randomly divided in 3 groups, all engaged in 10 sessions therapy; first group will receive high intensity laser therapy, second group will receive low intensity laser therapy and the third group will receive placebo laser. All groups will receive routine physical therapy treatments. At the end of the treatment sessions and also 2 weeks after finishing the treatment the previously mentioned assessments will be done again. Anova test will be used for between group comparisons, if the data present with normal distribution otherwise Kruskal wallis test will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707012829N1**
Registration date: **2017-07-18, 1396/04/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of High intensity laser therapy (HILT) versus low intensity laser therapy (LILT) on pain and functional improvement of the patients with non-specific chronic low back pain

Public title
Effect of laser therapy on chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age range between 18 -40 years; Low back pain from 3 months to one year; Pain level between 30 – 60 mm (VAS scale); No physical therapy and manual therapy in past 3 months; Gaining 20% to 70% of the score of the disability level questionnaire Exclusion criteria: Spondylolisis and Spondylolisthesis; Disc herniation; Inability to sit, stand and forward bending for the short time due to severe pain or weakness or balance impairment; Vertebral anomaly; Pregnant women; History of low back and pelvic surgery; Diabetes, Rheumatoid arthritis and any kind of sensory impairment like neuropathy
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences, Zand Avenue, Shiraz, Iran
City
Shiraz
Postal code
7134814336
Approval date
2017-05-20, 1396/02/30
Ethics committee reference number
IR.SUMS.REC.1396.30

Health conditions studied

1

Description of health condition studied
Low back pain
ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified Backache NOS

Primary outcomes

1

Description
Pain
Timepoint
End of the treatment sessions and two weeks after finishing the intervention
Method of measurement
Visual Analogue Scale

2

Description
Disability level
Timepoint
End of the treatment sessions and two weeks after finishing the intervention
Method of measurement
Oswestry disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
High intensity laser therapy
Category
Rehabilitation

2

Description
Low intensity laser therapy
Category
Rehabilitation

3

Description
Placebo laser therapy

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
fars oil industry health clinic, physiotherapy ward
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Kambiz Eskandari
Street address
Central building of Shiraz University of Medical Sciences, Zand Avenue, Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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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