Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of dynamic neuromuscular stability (DNS) and low-level laser therapy on the muscle function and pain in People with low back pain from muscle weakness

Protocol summary

Study aim
Determining the effects of dynamic neuromuscular stability (DNS) and low-level laser therapy on the muscle function and pain in People with low back pain from muscle weakness

Design
Clinical trial with intervention and control groups, 40 female randomly assigned to 4 groups

Settings and conduct
Forty women with chronic non-specific low back pain were selected from 100 people and then randomly paired with a pre-test pain intensity score of 3 to 6 on the visual analogue scale and divided into four groups: combination of exercise and low-level laser, exercise, low-level laser and control

Participants/Inclusion and exclusion criteria
Inclusion criteria: Female; Non-Specific low back pain from muscle weakness; Duration of low back pain more than three months; Pain intensity between 3 and 6 on the visual pain scale Exclusion criteria Exclusion criteria: Use of anti-inflammatory and analgesic medications

Intervention groups
Intervention group 1: Exercise, Subject will perform exercises for 8 weeks, 3 sessions per week, each session lasting 90 minutes. Initially, they will perform myofascial release exercises for 25 minutes, stretching exercises for 15 minutes, then DNS exercises for 40 minutes along with breathing exercises, and finally cool down exercises for 10 minutes.exercises.Intervention group 2: low-level laser therapy, Subjects undergo low-level laser treatment on specific days and for a specific number of sessions Intervention group 3: Exercise with low-level laser therapy, Subject undergoes low-level laser and Exercise. Intervention group 4: Subjects will be controlled without exercise and without low-level laser

Main outcome variables
Chronic non-Specific Low Back Pain, movement function, quality of life, functional disability, lumbar spine range of motion, depression Inventory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250508065647N1**
Registration date: **2025-06-22, 1404/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-22, 1404/04/01**
Update count: **0**

Registration date
2025-06-22, 1404/04/01

Registrant information

Name
Atefeh Rafieeamjad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3267 1146

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-08, 1404/03/18

Expected recruitment end date
2025-06-23, 1404/04/02

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dynamic neuromuscular stability (DNS) and low-level laser therapy on the muscle function and pain in People with low back pain from muscle weakness

Public title

The effect of exercise and laser therapy on the muscle function and pain in People with low back pain from muscle weakness

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender Non-Specific low back pain from muscle weakness Confirmation of the type of low back pain with clinical examination and paraclinical evidence Duration of low back pain more than three months Age range 40 to 50 years Pain intensity between 3 and 6 on the visual pain scale

Exclusion criteria:

Aggravation of pain and disability with exercise Trauma or surgery during exercise Participation in regular weekly exercise activity Medical prohibition against participation in exercise activity Use of anti-inflammatory and analgesic medications

Age

From **40 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Pairing of participants: First, a VAS pre-test will be administered to all(with chronic non-specific low back pain, without discopathy) and based on the participants' pre-test scores, they will be divided into pairs with similar pain intensity scores between 3 and 6 on the visual analogue scale. Random assignment: Each pair will be randomly assigned to one of 4 groups: exercise and low-level laser, exercise group, laser group, and control group(10 people in each group. The intervention (exercise and low-level laser) will not be applied to the control group. Finally, a post-test will be administered and the data will be analyzed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee on Research Islamic Azad University - Marvdasht Branch

Street address

Marvdasht: Three kilometers of Persepolis Boulevard. Islamic Azad University of Marvdasht

City

Marvdasht

Province

Fars

Postal code

73711-13119

Approval date

2025-01-15, 1403/10/26

Ethics committee reference number

IR.IAU.M.REC.1403.560

Health conditions studied

1

Description of health condition studied

chronic non-specific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

low back pain

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring muscle pain intensity using a visual analog scale

2

Description

Endurance of trunk flexor muscles

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring trunk flexor muscle endurance with modified sit-up tes

3

Description

Endurance of trunk extensor muscles

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring the endurance of the trunk extensor muscles using the trunk lift test (extensor endurance)

4

Description

Strength of trunk flexor muscles

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring the strength of trunk flexor muscles with a dynamometer

5

Description

Strength of trunk extensor muscles

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring the strength of trunk extensor muscles with a dynamometer

6

Description

Flexibility

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring the flexibility of the back and hamstring muscles with the Sit and Reach test

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring quality of life with the SF36 quality of life questionnaire

2

Description

Depression Inventory

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring depression Inventory using the modified version of the Beck Depression Inventory

3

Description

Functional disability

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring functional disability with Oswestry Disability Index

4

Description

Range of motion of the lumbar spine

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Measuring the range of motion of the lumbar spine with the modified-modified schober test

Intervention groups

1

Description

Intervention group 1: Exercise; Ten female subjects will perform dynamic neuromuscular stability (DNS) exercises with myofascial release for 8 weeks, 3 sessions per week, each session lasting 90 minutes, as follows: First, 25 minutes of myofascial release exercises and 15 minutes of stretching exercises, then 40 minutes of DNS exercises with breathing exercises, and finally 10 minutes of cool-down exercises.

Category

N/A

2

Description

Intervention group 2: Low-level laser; Ten female subjects will undergo low-level laser on specific days and for a specific number of sessions. Also, the following model power meter will be used to measure the optical power of the device every two weeks (by a researcher who is not involved) and the type of laser device PHOTONCARE model Moonlight and Starlight (2020) made in Germany

Category

N/A

3

Description

Intervention group 3: Exercise and low-level laser; Ten female subjects will perform dynamic neuromuscular stability (DNS) exercises with myofascial release for 8 weeks, 3 sessions per week, each session lasting 90 minutes, as follows: First, 25 minutes of myofascial release exercises and 15 minutes of stretching exercises, then 40 minutes of DNS exercises with breathing exercises, and finally 10 minutes of cool-down exercises and also subjects will undergo low-level laser on specific days and for a specific number of sessions. Also, the following model power meter will be used to measure the optical power of the device every two weeks (by a researcher who is not involved) and the type of laser device PHOTONCARE model Moonlight and Starlight

(2020) made in Germany

Category

N/A

4

Description

Control group 4: No intervention; Ten female subjects will be given control without Exercise and without low-level laser

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Health Land Institute

Full name of responsible person

Parvin Salsali

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U 1, No. 42, Shahid Mehdi Salimian Aly, Bahar Azadi Ave, Azadi Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Atefeh Rafieeamjad

Position

Teacher

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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