Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of lumbar spine muscles myofascial release with remote myofascial release of lower limb muscles on the ultrasonography parameters of myofascial system and function in patient with chronic nonspecific low back pain

Protocol summary

Study aim
Comparative study of myofascial release of lumbar spine muscles with lower limb muscle release on myofascial system parameters and performance in patients with chronic non-specific back pain.

Design
The study is a clinical trial with a control group, with parallel, double-blind, randomized groups. . People are divided into three groups by simple randomization method

Settings and conduct
Non-random sampling of people with non-specific chronic back pain referring to physiotherapy clinics was selected in a simple and accessible way, then after selecting the sample with entry and exit criteria, the participants were divided into three groups by simple randomization method.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study included people aged 18-45 who had non-specific chronic back pain that lasted more than 3 months and caused muscle involvement, and their VAS was less than 3, which means it was not an acute problem. Exclusion criteria: pregnancy, tumor Spinal cord, infection or fracture, infectious, vascular, endocrine, metabolic or neoplastic autoimmune disease, systemic disease, fibromyalgia, cauda equina syndrome, previous spine surgery or lower extremity musculoskeletal injuries, previous experience in myofascial therapy or history of rehabilitation therapy Do not have back pain in the past two months

Intervention groups
Individuals in the two intervention groups, a lumbar fascia release group and a lower extremity fascia release group, receive four sessions twice a week along with routine electrotherapy. In the control group, only routine electrotherapy is performed.

Main outcome variables
Muscle thickness, pain, disability

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160808029264N17**
Registration date: **2024-05-18, 1403/02/29**
Registration timing: **prospective**

Last update: **2024-05-18, 1403/02/29**
Update count: **0**

Registration date
2024-05-18, 1403/02/29

Registrant information

Name
Rasool Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3344 1022

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-31, 1403/06/10

Expected recruitment end date
2025-09-01, 1404/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of lumbar spine muscles myofascial release with remote myofascial release of lower limb muscles on the ultrasonography parameters of myofascial system and function in patient with chronic nonspecific low back pain

Public title

the effect of fascia release in non-specific chronic back pain patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria for the study included people aged 18-45 who had non-specific chronic back pain that lasted for more than 3 months and caused muscle involvement and their VAS was less than 3, which means it was not an acute problem.

Exclusion criteria:

Pregnancy spinal cord tumor infection or fracture infectious, vascular, endocrine, metabolic or neoplastic autoimmune disease, systemic disease, fibromyalgia, cauda equina syndrome, previous spine surgery or lower extremity musculoskeletal injuries, previous experience in myofascial therapy or Do not have a history of rehabilitation treatment for back pain in the last two months

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using a random table, the patient will be randomly assigned into the groups by choosing the number.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not know which group they are in. The evaluator of study outcomes will also not know about the grouping of patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comitee of Semnan University of Medical Sciences

Street address

Basij Blvd.,Semnan., Semnan Province

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semnan

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Postal code

99951-35198

Approval date

2024-03-10, 1402/12/20

Ethics committee reference number

IR.SEMUMS.REC.1402.315

Health conditions studied

1

Description of health condition studied

non specific chronic low back pain

ICD-10 code

M54.06

ICD-10 code description

Panniculitis affecting regions of neck and back, lumbar region

Primary outcomes

1

Description

Muscle thickness

Timepoint

The first session and the last session

Method of measurement

sonography

2

Description

pain

Timepoint

The first session and the last session

Method of measurement

VAS

3

Description

disability

Timepoint

The first session and the last session

Method of measurement

The Quebec Back Pain Disability Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groIntervention group: The interventions performed in this group include the release of spinal fascia such as quadratus lumborum, erector spinae, thoracolumbar fascia and soas for four sessions twice a week and each session thirty minutes of release on each side. Routine electrotherapy is also performed.

Category

Rehabilitation

2

Description

Intervention grouIntervention group: The interventions performed in this group include the release of lower limb fascia such as gastrocnemius, soleus, plantar fascia, and hamstring for four sessions twice a week and each session thirty minutes of release on each side. Routine electrotherapy is also performed.p:

Category

Rehabilitation

3

Description

Control group: routine electrotherapy is performed in this group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center,. Semnan University of Medical Scinces., Semnan., Iran.

Full name of responsible person

Dr Rasool Bagheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source

Semnan 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

mansourehrahbary

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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