

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

Protocol summary

Study aim

The aim of this study was to evaluate The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

Design

30 Individuals with non-specific chronic low back pain participate in this Double blind study, which is randomly divided into two groups of intervention and control using four random blocks.

Settings and conduct

Volunteer participants with non-specific chronic low back pain referred to the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria in this study Complete satisfaction to participate in this study, chronic non-specific low back pain with a minimum period of three months, age between 20-45, pain intensity 3-6, bilateral shortening of psoas major muscle, degree of disability 6-18 (from 24 points). Non-inclusion criteria include pregnancy, having systemic fibromyalgia, Cauda equina syndrome, spinal tumor, having autoimmune, infectious, vascular, endocrine, metabolic and neoplastic diseases, having previous experience of myofascial treatment or history of low back pain rehabilitation treatment Over the past two months, there has been a history of spinal surgery and other contraindications to myofascial therapy.

Intervention groups

The intervention group receives the technique of releasing the myofascia of psoas major muscle for four periods in two weeks (twice a week) for forty minutes on both sides. The control group symbolically receives the technique of releasing the myofascia of the Psoas major muscle in four periods of two weeks and for forty minutes on both sides.

Main outcome variables

Angular velocity, Angular displacement, Maximum range of motion, Relative phase, Maximum and minimum angular phase and time to reach them, Disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150602022539N12**

Registration date: **2022-04-19, 1401/01/30**

Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**

Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name

Ziaeddin Safavi Farokhi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-29, 1401/02/09

Expected recruitment end date

2022-06-25, 1401/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

Public title

The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete satisfaction to participate in this study People with nonspecific chronic low back pain with a minimum period of three months Age between 20-45 Pain intensity 3-6 Bilateral shortening of psoas major muscle Disability grade 6-18 (from 24 points)

Exclusion criteria:

Pregnancy Having systemic fibromyalgia, Cauda equina syndrome, spinal tumor Having autoimmune, infectious, vascular, endocrine, metabolic and neoplastic diseases History of spinal surgery and other criteria contraindicating use of myofascial therapy Have previous experience in myofascial treatment or a history of low back pain rehabilitation treatment in the last two months

AgeFrom **20 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, Permuted block randomization will be used for randomization, which includes 4 blocks (2 participants in the intervention group and 2 participants in the control group). Random allocation software is also used for randomization tools. In order to create an allocation concealment, each random sequence created is recorded on a card and the cards are placed in sealed opaque envelopes, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, according to the order of arrival, one of the envelopes is opened in order and the

assigned group of that participant is identified.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blindness will be done in the participants. Participants from both groups will be admitted at different times for evaluation and intervention and will not be aware of the type of intervention of the other group. The implementation phase of this research is performed by another physiotherapist who is skilled in the field of manual therapies and the researcher who evaluates the outcome and Data analysis is involved. It is unaware of the grouping of participants and receives the data without knowing the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan, km 5 of Damghan road, Semnan University of Medical Sciences

City

semnan

Province

Semnan

Postal code

3519899951

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.SEMUMS.REC.1400.339

Health conditions studied**1****Description of health condition studied**

Non specific chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Angular velocity during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

2

Description
Angular displacement during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

3

Description
Maximum range of motion during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

4

Description
Disability
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Ronald-Morris Questionnaire

5

Description
Relative phase during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

Secondary outcomes

1

Description
Minimum phase angle during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

2

Description

maximum phase angle during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

3

Description
Time to reach the maximum phase angle during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

4

Description
Time to reach the minimum phase angle during stand to sit and sit to stand
Timepoint
Before and immediately after the two-week intervention
and one month after the intervention
Method of measurement
Motion analysis device

Intervention groups

1

Description
Control group: Symbolically receives the technique of releasing the myofascia of the Psoas major muscle in four periods of two weeks and for forty minutes on both sides
Category
Rehabilitation

2

Description
Intervention group: receives the technique of releasing the myofascia of psoas major muscle for four periods in two weeks (twice a week) for forty minutes on both sides.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences
Full name of responsible person
Ziaeddin Safavi Farokhi

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Mashahir Square, in front of Helal Ahmar, Semnan

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

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

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**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Position

Ph.D, Assistant Professor

Latest degree

Ph.D.

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