Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 myofacial 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

Email address

zsafavi@semums.ac.ir

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 intensity3-6 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 myofacial treatment or a history of low back pain rehabilitation treatment in the last two months
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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

Street address
Mashahir Square, in front of Helal Ahmar, Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
ziasafavi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kookhaei
Street address
Semnan, Mashahir Square, in front of the Red Crescent Center of Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
p-kokha@yahoo.com
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
Street address
Rehabilitation faculty, Semnan University of Medical Sciences, Kilometer 5 of Damghan Road, Semnan
City
Semnan
Province
Semnan
Postal code
3013138111
Phone
+98 23 3365 4180
Email
ziasafavi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
ziaeddin Safavi Farrokhi
Position
Ph.D, Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Rehabilitation faculty, Semnan University of Medical Sciences, Kilometer 5 of Damghan Road, Semnan
City
Semnan
Province
Semnan
Postal code
3013138111
Phone
+98 23 3365 4180
Email
ziasafavi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
ziaeddin Safavi Farrokhi
Position
PhD, Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Semnan, km 5 of Damghan road, Semnan University

of Medical Sciences, Faculty of Rehabilitation

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
ziasafavi@yahoo.com

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