Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of the effect of lumbar and lower limbs posterior superficial backline myofascial release on elastic coefficient, thickness and pain in non-specific chronic low back pain patients

Protocol summary

Study aim

Comparative study of myofascial release of lumbar region and posterior-superficial pathway of lower extremity myofacia on pain, elastic coefficient and fascia thickness of lumbar region in patients with chronic non-specific low back pain

Design

The clinical trial has a control group with parallel groups. non-randomized and double blind on at least 30 patients

Settings and conduct

The study place is Tarbiat Modares University. After the examinations to enter the study, participants are divided into three groups and at the end of interventions, They undergo an ultrasound by someone who is blind of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with chronic non-specific low back pain with at least 12 months of history of low back pain, shortness of the lumbar fascia and lower extremities, pain score between 4 and 6 on the VAS scale, age range 35 to 50, BMI is between 18.5 and 30. People who have a history of disease and deformity of the spine and lower extremities, a history of underlying diseases such as rheumatic diseases, heart disease, etc. do not qualify for the study. Attendees are excluded from the study if they engage in strenuous activity, pregnancy, and unwillingness to continue.

Intervention groups

The intervention group includes patients with chronic nonspecific low back pain who receive myofascial lumbar relief intervention. The intervention group includes patients with chronic nonspecific low back pain who receive myofascial intervention for lower extremity fascia. The control group includes patients with chronic nonspecific low back pain who receive routine physiotherapy.

Main outcome variables

pain changes; Lumbar and lower extremity flexibility changes; Changes in the range of motion of lumbar and lower limbs; Changes in the elastic coefficient of myofascial lumbar tissue

General information

Reason for update

Due to the prevalence of the Covid 19 pandemic, the sampling date changed. Of course, in the previous registration, the date of the sampling was incorrectly registered before the date of the trial confirmation, which was corrected. Except for the date of sampling, the other recorded cases did not change.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200423047173N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **prospective**

Last update: **2021-07-21, 1400/04/30**
Update count: **1**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

Hassan Tamartash

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of lumbar and lower limbs posterior superficial backline myofascial release on elastic coefficient, thickness and pain in non-specific chronic low back pain patients

Public title
Effect of myofascial release on low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with chronic nonspecific low back pain with a history of at least 12 months of low back pain. Shortness in lumbar myofascial and posterior-superficial pathway of lower extremity myofascia. Having a pain score between 4 and 6 on the VAS pain scale Body mass index between 18.5 and 30.
Exclusion criteria:
History of spine and lower limb surgery Existence of major deformities in the spine such as: scoliosis, kyphosis, etc. Infection and history of rheumatic, infectious, cardiovascular diseases, etc. Psychopathy Disorders of the vestibular and visual systems. Taking corticosteroids and history of lumbar injections (oral or steroid injections). Pregnancy Perform intense physical activity during the study. Inability and unwillingness to continue study.
Age
From **35 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present study, patients (in two groups of myofascial lumbar and lower limb release) and co-evaluator who performs ultrasound before and after the intervention, will be unaware of the patient's exposure (myofascial lumbar or lower limb).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares University
Street address
Post Cod:14115-111, Nasr Bridge, Jalal Al Ahmd Ave, Tehran
City
Tehran
Province
Tehran
Postal code
4115-111
Approval date
2019-10-07, 1398/07/15
Ethics committee reference number
IR.MODARES.REC.1398.126

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
Lumbar fascia elastic coefficient
Timepoint
The beginning of the study, the end of the second week, the end of the fourth week
Method of measurement
Ultrasound device

2

Description
Lumbar muscles elastic coefficient
Timepoint
The beginning of the study, the end of the second week,

the end of the fourth week

Method of measurement

Ultrasound device

Secondary outcomes

1

Description

Cuff and hamstring muscle flexibility

Timepoint

The beginning of the study, the end of the second week, the end of the fourth week

Method of measurement

Goniameter

2

Description

Lumbar pain

Timepoint

The beginning of the study, the end of the second week, the end of the fourth week

Method of measurement

Visual analoge scale

3

Description

Pelvic rotation angle

Timepoint

The beginning of the study, the end of the second week, the end of the fourth week

Method of measurement

Inclinometer

4

Description

Lumbar flexion angle

Timepoint

The beginning of the study, the end of the second week, the end of the fourth week

Method of measurement

Flexible ruler

Intervention groups

1

Description

Intervention group 1: Myofascial release of lumbar region in patients with chronic nonspecific low back pain

Category

Diagnosis

2

Description

Intervention group 2: Myofascial release of posterior-superficial pathway of lower extremities in patients with chronic nonspecific low back pain

Category

Diagnosis

3

Description

Control group: Routine physiotherapy (ultrasound and tens) of the lumbar region in patients with nonspecific low back pain

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Araz Physiotherapy Clinic

Full name of responsible person

Hassan Tamartash

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No. 120, Unit 9, Mirzababaei St., Punak, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

farid Bahrpeyma

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Post Cod:14115-111, Nasr Bridge, Jalal Al Ahmd Ave, Tehran

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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

Tarbiat Modares 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
Tarbiat Modares University

Full name of responsible person
Hassan Tamartash

Position
Phd candidate student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All potential data can be shared after unidentified individuals

When the data will become available and for how long
Access period starts 12 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to perform any kind of analysis on the data, coordination is required

From where data/document is obtainable

Send a message to the mentioned e-mail address, named Hassan Tamratash. h.tamartash@modares.ac.ir

What processes are involved for a request to access data/document

After sending the message and making the necessary arrangements, the data will be sent for a maximum of one month.

Comments