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 myofascia 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)
Phone
+98 21 8288 3819
Email address
h.tamartash@modares.ac.ir

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

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

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**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**
Goniometer

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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

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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

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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

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**Intervention groups**

1

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

**Category**
Diagnosis

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2

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

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**Recruitment centers**

1

**Recruitment center**
Name of recruitment center
Araz Physiotherapy Clinic

**Full name of responsible person**
Hassan Tamartash

**Street address**
No. 120, Unit 9, Mirzababaei St., Punak, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1476773313

**Phone**
+98 21 4489 2775

**Email**
h.tamartash@modares.ac.ir

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**Sponsors / Funding sources**

1

**Sponsor**
Name of organization / entity
Tarbiat Modares University

**Full name of responsible person**
farid Bahrpeyma

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

**City**
Tehran

**Province**
Tehran

**Postal code**
14115-111

**Phone**
+98 21 8288 3819

**Email**
BAHRPEYF@modares.ac.ir

**Grant name**

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**Grant code / Reference number**

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**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**

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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
Street address
Post Cod:14115-111, Nasr Bridge, Jalal Al Ahmd Ave, Tehran
City
Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3819
Fax
Email
h.tamartash@modares.ac.ir

Person responsible for scientific 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
Street address
Post Cod:14115-111, Nasr Bridge, Jalal Al Ahmd Ave, Tehran
City
Tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3819
Fax
Email
h.tamartash@modares.ac.ir

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**