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
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Name of organization / entity
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Recruitment status
Recruitment complete
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
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Tehran
Province
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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

**Category**
Diagnosis

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**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**
Araz Physiotherapy Clinic

**Full name of responsible person**
Hassan Tamartash

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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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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Person responsible for general inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Hassan Tamartash
Position
Phd candidate student
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Person responsible for scientific inquiries

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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