Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Measurements of lumbar multifidus muscle thickness using ultrasound in chronic low back pain patients, before and after physical therapy exercises

Protocol summary

Study aim
To study whether strengthening of the lumbar multifidus muscles can be more effective than the MF muscle stabilization in restoration of the muscle size.

Design
Two parallel groups (one as control and one as intervention) with random assignment of the subjects into two groups of 12.

Settings and conduct
For all subjects of each group, the trials continued in 24 sessions distributed over 8 weeks and the MF muscles were measured in the beginning of the first session and at the end of the last session

Participants/Inclusion and exclusion criteria
only those CLBP patients with a pain intensity above 3 were selected. Oppositely, patients with a history of sacroiliac dysfunction, invasive surgical operations with alteration of the normal anatomy of the patient (e.g., implant) on abdomen, pelvis, and lower extremity, respiratory diseases, neurological disorders, pelvic fracture and dislocation, scoliosis and structural deformities of spine, spine surgery, malignancies, rheumatic diseases, or other systemic diseases, acute back trauma, spondylolysis and spondylolisthesis, and pregnancy or caesarian section in the last two months were excluded.

Intervention groups
12-person group of chronic low back pain patients who underwent hip abductor strengthening exercises

Main outcome variables
Statistical significance (p-value) of the change in the average MF muscle thickness, pain, and disability scores along with for each group

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201119049444N1**
Registration date: **2020-12-13, 1399/09/23**
Registration timing: **retrospective**

Last update: **2020-12-13, 1399/09/23**
Update count: **0**

Registration date
2020-12-13, 1399/09/23

Registrant information

Name
Mahnaz Aboufazeli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-10, 1396/10/20

Expected recruitment end date
2018-01-24, 1396/11/04

Actual recruitment start date
2018-02-20, 1396/12/01

Actual recruitment end date
2018-02-27, 1396/12/08

Trial completion date
2018-05-19, 1397/02/29

Scientific title
Measurements of lumbar multifidus muscle thickness

using ultrasound in chronic low back pain patients, before and after physical therapy exercises

Public title
Recovery of muscle size and pain improvement in patients with a chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female chronic low back pain patients with a pain intensity above 3 score when using Visual Analog Scale
Exclusion criteria:
patients with a history of sacroiliac dysfunction, invasive surgical operations with alteration of the normal anatomy of the patient (e.g., implant)major surgeries on abdomen, pelvis, and lower extremity, respiratory diseases, neurological disorders, pelvic fracture and dislocation, scoliosis and structural deformities of spine, spine surgery, malignancies, rheumatic diseases, or other systemic diseases, acute back trauma, spondylolysis and spondylolisthesis, and pregnancy or caesarian section in the last two months were excluded.
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
With consideration of the minimum subjects needed for a reliable statistical analysis, a total of 24 participants who were eligible for random allocation between two groups, were selected. To avoid potential bias in allocation of the participants, their hospital admission IDs were shuffled using MicroSoft Office Excel software package. Then, the first 12 participants appeared in the resultant output column of the software were allocated to the first group (control group) and the second 12 participants appeared in that column were allocated to the second group (intervention group).
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients did not know whether they are receiving the conventional treatment or the interventional treatment. The radiologist who performed muscle thickness measurements also did not the group a patient was coming from. The data analyst knew the group as 1 and 2, so he also did not know which group is conventional and which one is interventional.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
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Province
Tehran
Postal code
14496-14535
Approval date
2016-12-10, 1395/09/20
Ethics committee reference number
IR.IUMS.REC 1395.9211342209

Health conditions studied

1

Description of health condition studied
Chronic low back pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Thickness of the lumbar multifidus muscle, pain intensity, and disability index
Timepoint
8 weeks with 3 sessions each (24 sessions)
Method of measurement
An ultrasound device is used for muscle thickness measurements, a linear scale is used for marking the pain intensity by patients (Visual Analog Scale), and finally a questionnaire is used to record the disability index (Oswestry).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: hip abductor strengthening exercises 3 times a week and total period of 8 weeks (24 sessions). Each session started with 10 min warm-up period consisted of 5 min stationary biking at a moderate pace and 5 min back stretching exercises. During the back stretching, the low back sustained rotation from supine position, single and double knee to chest from supine position, alternate spinal flexion-extension from 4-point kneeling position, trunk forward stretching while sitting on the heels and with trunk parallel to the floor, side bending in standing position with and without contralateral arm elevation. Then, the patients received the hip abductor strengthening exercises consisting of abduction during four separate positions: supine, side lying, and standing.

Category
Rehabilitation

2

Description
Control group: Stabilization exercises 3 times a week and total period of 8 weeks (24 sessions). The stabilization exercises were performed in 6 steps including: 1) segmental control exercises (SCE) with emphasis on training of isolated contraction of the transversus abdominis, multifidus, and pelvic floor muscles, 2) SCE with emphasis on co-contractions of the above-mentioned muscles in the prone, supine, and four-point kneeling positions, 3) SCE as a closed kinematic chain, 4) SCE extension by adding a low weight (0.5-1.5 kg) to create leverage of the limbs, 5) application of SCE in functional situation, and 6) co-contraction of the transversus abdominis and multifidus, muscles during application of an external load, complication of movements, increased load with the lumbar spine in the correct position, and addition of a co-contraction pattern to light aerobic activities such as walking.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Mahnaz Aboufazeli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mahnaz Aboufazeli

Position
Researcher

Latest degree
Ph.D.

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
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available
Title and more details about the data/document
Results of multifidus muscle size measurements and pain intensity in chronic low back pain patients before and after stabilization and hip abductor strengthening treatments
When the data will become available and for how long
From January 2021
To whom data/document is available
Public but mainly medical scientists and healthcare providers
Under which criteria data/document could be used
Non-profit
From where data/document is obtainable
Email corresponding author
What processes are involved for a request to access data/document
Within 2 business days after receiving the email request
Comments