

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

Country

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

City

Tehran

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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Akbari

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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