Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of dry needling compared to lumbar spine mobilization on pain, functional disability, quadratus lumborum and lumbar multifidus function, lumbar range of motion and pain pressure threshold in patients with non-specific chronic low back pain

Protocol summary

Study aim
The main objective of this study is to compare the effects of dry needling and lumbar spinal mobilization on pain intensity, functional disability, lumbar multifidus and quadratus lumborum muscles function, lumbar range of motion and pain pressure threshold in patients with chronic non-specific low back pain

Design
The present study will be a randomized, double-blind, sample size 56, double-dummy, controlled trial.

Settings and conduct
After selecting individuals with chronic non-specific low back pain by non-probability purposive sampling method, patients will be randomly assigned to two groups of dry needling plus sham mobilization (first group) and lumbar spine mobilization plus sham dry needling group (second group). In addition, participants in both treatment groups will receive routine physiotherapy (including low-power laser and core stability exercise). Both groups will be treated for 8 sessions over 4 weeks. This study is also a double-blind study in which the participants, the person evaluating the outcome, and the person analyzing the data will be blinded to the allocation of patients to the two treatment groups. This study will be performed in the Rehabilitation Sciences school of Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with chronic non-specific low back pain in the age range of 18 to 45 years old
exclusion criteria: Existence of complications that affect the treatment process and cases of prohibition of dry needling use or lumbar spinal mobilization

Intervention groups
In this study, the first group will receive Multifidus and Quadratus lumborum muscles dry needling plus sham mobilization and the second group will receive sham dry needling in addition to lumbar spine mobilization.

Main outcome variables
Function based on Oswestry Disability Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210706051802N1**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **prospective**

Last update: **2024-04-09, 1403/01/21**
Update count: **1**

Registration date
2021-11-09, 1400/08/18

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2023-08-20, 1402/05/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of dry needling compared to lumbar spine mobilization on pain, functional disability, quadratus lumborum and lumbar multifidus function, lumbar range of motion and pain pressure threshold in patients with non-specific chronic low back pain

Public title
The effect of dry needling compared to lumbar spine mobilization in chronic non-specific low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 18 to 45 years. Moderate pain intensity (between 30 to 60) based on Numerical Pain Rating Scale (0 means no pain and 100 is the most imaginable pain). Patients with trigger points in the quadratus lumborum and lumbar multifidus muscles. The patient's symptoms are provoked with passive accessory intervertebral movements (PAIVM) on at least one level of the lumbar spine vertebrae. Patients are able to read and write Persian.
Exclusion criteria:
Complications that affect the treatment process such as systemic diseases, neurological disorders, inflammatory conditions, infectious conditions, structural and degenerative changes, metabolic bone diseases and bleeding disorder. History of lumbar surgery. Fracture. People who have received exercise therapy or manual treatments or dry needling for the lumbar region in past month. Have active cancer. Pregnancy. Needle phobia. Long history of steroid use.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible chronic non-specific low back pain patients will be randomized to an intervention group (dry needling in addition to sham spinal mobilization and routine physical therapy) and a control group (sham dry needling in addition to spinal mobilization and routine physical therapy) with a ratio of 1:1. Randomized allocation will be performed by using permuted block randomization method, which consists of four-letter blocks made of letters A and B. Then, the random treatment list that will be obtained at the end of the random allocation task will be placed in letters A and B inside the sealed and numbered envelopes (A letter indicates dry needling in addition to sham spinal mobilization and letter B indicates sham dry needling in addition to spinal mobilization). The random assignment process will be performed by someone outside the research team before the study begins. After the initial evaluation of the patient by the examiner, the numbered envelopes will be presented to him/her according to the ordinal number of each person admitted to the study. Finally, after each patient enters the treatment sessions, the therapist will adjust the treatment interventions based on the letters in the envelope. Patients are asked not to provide their grouping information to the assessor to prevent data contamination.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants, outcome assessor and data analyzer will be kept blind to being assigned to the study groups. Blinding method: A) Participants: Participants will not have information about which treatment group they have entered, and also in each treatment group, people will receive a real treatment in addition to sham of the real treatment in the other group (the first group includes dry needling in addition to sham spinal mobilization and the second group includes sham dry needling in addition to spinal mobilization) were used so the participants could not guess which treatment group they have entered. B) Outcome assessor: Outcome assessment will be performed by a person who does not know the grouping of the individuals and the treatments performed in each treatment group. C) Data analyzer: Data analysis will be performed by a person who does not know the grouping of individuals and the treatments performed in each treatment group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Dormitory of the school of Rehabilitation of Iran University of Medical Sciences, Shah nazari Ave., Madar square, Mirdamad Blvd.

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Tehran
Province
Tehran
Postal code
1545913487
Approval date
2021-10-16, 1400/07/24
Ethics committee reference number
IR.IUMS.REC.1400.651

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
Functional disability based on Oswestry Disability Index
Timepoint
Functional disability measurement before intervention and 7 days after intervention
Method of measurement
Oswestry Disability Index

Secondary outcomes

1

Description
Range of motion
Timepoint
Before intervention and 7 days after intervention
Method of measurement
Inclinometer

2

Description
Lumbar multifidus and quadratus lumborum muscles functional change (thickness change)
Timepoint
Before intervention and 7 days after intervention
Method of measurement
Ultrasound

3

Description
Pain pressure threshold
Timepoint
Before intervention and 7 days after intervention
Method of measurement
Algometer

4

Description
Pain intensity based on Numerical Pain Rating Scale
Timepoint
Pain intensity measurement before intervention and 7 days after intervention
Method of measurement
Numerical Pain Rating Scale

Intervention groups

1

Description
Intervention group: The treatments of this group will include dry needling plus sham mobilization for lumbar spine and routine physiotherapy: A) Dry needling: The method of performing the dry needling technique will be based on the method presented by Dommerholt and Fernandez-de-las-Penas. The needles will be inserted to obtain local twitch response, and this process will continue until no more local twitch response occurs in each session. Then the needles will be left in place for 20 minutes: 1) Multifidus dry needling technique: the patient will be placed in a prone position with a pillow under their belly to accommodate lumbar lordosis and two lengths of sterile, disposable, 0.30 mm × 75 mm and 0.30 mm× 50 mm solid filament needle (Tony, china) will be used. The length of the needle for each patient will be selected based on the size of the patient. the needles will be inserted into the lumbar multifidus muscles, 1.5 to 2 cm lateral to the spinous process of all lumbar vertebrates, perpendicular to the lamina (after piercing the skin, needles are directed inferomedially). 2) Quadratus lumborum dry feeling technique: The patient will be placed in the side lying position with the side to be treated facing up. If needed, the patient can bring the ipsilateral arm overhead with a pillow placed under the torso to improve access to the muscle. Next, the therapist's fingers will move slightly posterior and press deeply to identify the lateral border of the quadratus lumborum muscle, which is just lateral and ventral to the iliocostalis lumborum muscle. Then, a sterile, disposable, 0.30 mm * 75 mm solid filament needle (Tony, china) will be aimed straight downward in the direction of the transverse process, followed by slight anterior, posterior, and caudal needling to explore the entire muscle. B) Sham mobilization for lumbar spine will be done in the same way as the real mobilization, with the difference that the mobilization will be applied only on the skin surface (less than the first degree of Maitland mobilization). C) Routine physiotherapy includes low power laser and core stability exercises. Low power diode laser (Arman Pouya, made in Iran) with a wavelength of 808 nm, output power of 800 mW, energy of 50 joules per square centimeter, in the form of pulse frequency with a working period of 80%, will be used in place of the quadratus lumborum muscles and 1.5 to 2 cm out of the lumbar Spinous process on both sides, for

one minute for each point and a total time of ten minutes. Core stability exercises will consist of three stages of exercises, The first week will include the exercises of the first stage, the second and third weeks include the first and second stage exercises, and the fourth week will include all of the exercises. The first stage exercises will include: abdominal drawing, abdominal bracing lift and alternative arm and leg lift, the second stage exercises will include: unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up, sit back and the third stage exercises will include: bridging on swiss ball, diagonal curl up with elastic band, trunk extension on swiss ball, unilateral bridging with weight cuff and forward step up. Each exercise will be repeated 10 times and each repetition will last 10 seconds and there will be one minute break between each exercise. This group will be treated for 8 sessions over 4 weeks.

Category

Rehabilitation

2

Description

Control group: The treatments of this group will include sham dry needling plus lumbar spine mobilization and routine physiotherapy: A) Sham Dry needling will be performed for lumbar multifidus and quadratus lumborum muscles in such a way that all things are like the real dry needling technique. The difference is that the needle will be inserted only on the surface of the skin and will be left in place for 20 minutes. B) To perform lumbar spine mobilization, the anterior-posterior mobilization technique will be used, which is a common and safe treatment for low back pain, during which it is performed pushing the heel (pisiform grip) or thumbs (thumb grip) to the spine and can immediately reduce pain and restore motor function. During mobilization the force will be applied in an oscillating manner, 3 times, each time for 1 minute, and a 20-second break will be given between each set. First, the complete physical orthopedic evaluation of manual therapies will be performed using the Maitland evaluation method. Then, based on the findings of the patient evaluation, the severity, rhythm and time of the operation and the degree of mobilization and the place of force (spine or lamina) are determined. To apply mobilization, the person will sleep in a prone position and will use the heel of his hand or thumbs to apply force to the first to fifth vertebrae of the lumbar spine. In segments that do not have a problem based on evaluation, first Maitland anterior-posterior mobilization will be applied to the spine of the segment. C) Routine physiotherapy will include low-power laser and core stability exercises. Low power diode laser (Arman Pouya, made in Iran) with a wavelength of 808 nm, output power of 800 mW, energy of 50 joules per square centimeter, in the form of pulse frequency with a working period of 80%, will be used in place of the quadratus lumborum muscles and 1.5 to 2 cm out of the lumbar Spinous process on both sides, for one minute for each point and a total time of ten minutes. Core stability exercises will consist of three stages of exercises, The first week will include the exercises of the first stage, the second and third weeks will include the first and second stage exercises, and the fourth week will include all of the exercises. The first stage exercises will include: abdominal drawing, abdominal bracing lift and alternative arm and leg lift, the second stage exercises will include: unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up, sit back and the third stage exercises will include: bridging on swiss ball, diagonal curl up with elastic band, trunk extension on swiss ball, unilateral bridging with weight cuff and forward step up. Each exercise will be repeated 10 times and each repetition will last 10 seconds and there will be one minute break between each exercise.This group will be treated for 8 sessions over 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation school of Iran university of medical science

Full name of responsible person

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Sponsors / Funding sources

1

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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

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Full name of responsible person
Hamide Mirzaie
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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
Yes - There is 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

Deidentified individual participant data collected for the primary and secondary outcome measures will be shared if necessary.

When the data will become available and for how long

Starting 6 months after publication.

To whom data/document is available

The data will be available for physical therapists working in academic institutions and also clinicians working in the field of musculoskeletal disorders.

Under which criteria data/document could be used

The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of low back pain.

From where data/document is obtainable

Applicants can contact Dr. Mohammad Reza Pourahmadi by email. Email address: pourahmadipt@gmail.com

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

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

Comments