# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## Effectiveness of Dry Needling on Pain, Functional Disability, Postural Control, and Pain Pressure Threshold in patients with Chronic Nonspecific Low Back Pain: A Double-blind Randomized Controlled Trial

## Protocol summary


**Study aim**

The aim of this study will be to investigate the effectiveness of dry needling on pain, functional disability, postural control and pain pressure threshold in patients with chronic nonspecific low back pain.

**Design**

The experimental design will be a randomized, sham controlled, double-blind, parallel assignment. Forty patients will be randomly divided into two groups with an allocation ratio of 1:1.The randomozation method is block balanced randomization.

**Settings and conduct**

The procedure will be conducted at school of rehabilitaion, Iran University of Medical Sciences. Forty patients will be randomly divided into two groups: Experimental group (n=20, dry needling+ routine physical therapy) and control group (n=20, sham dry needling + routine physical therapy). The intervention will be for six sessions, three weeks, twice a week. Outcomes will be examined at baseline and one week after the end of the intervention. The examiner will be blinded to the intervention procedure. Patients will be also blinded to which group they belong to.

**Participants/Inclusion and exclusion criteria**

Patients with chronic nonspecific low back pain, age between 18 to 45 years, moderate pain at rest and with trigger points in the lumbar multifidus muscle, will get involved in In this investigation. Some of the exclusion criteria are: pregnancy, non-musculoskeletal pathology, Specific low back pain, needle phobia, Inability to obtain prone lying, systemic disease and sacroiliac dysfunction.

**Intervention groups**

The experimental group will recieve dry needling of the lumbar multifidus muscle and routine physical therapy. The control group will recieve sham dry needling of the lumbar multifidus muscle and routine physical therapy.

**Main outcome variables**

1- Pain intensity based on 0-100 Numeric Pain Rating Scale 2- Functional disability based on The Persion version of Oswestry Disability Index


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211118053098N1**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**
Update count: **0**

**Registration date**

2021-12-13, 1400/09/22

**Registrant information**


**Name**

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**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-01-01, 1400/10/11

**Expected recruitment end date**

2022-07-22, 1401/04/31

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effectiveness of Dry Needling on Pain, Functional Disability, Postural Control, and Pain Pressure Threshold in patients with Chronic Nonspecific Low Back Pain: A Double-blind Randomized Controlled Trial

**Public title**
Effectiveness of Dry Needling in Patients With Chronic Nonspecific Low Back Pain
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients age between 18 to 45 years. Moderate pain at rest (between 30 and 60 in NPRS). Patients with trigger points in the lumbar multifidus muscle. Patients have the ability to speak and read Persian.
**Exclusion criteria:**
known pregnancy. Currently taking anticoagulant medications. Specific low back pain (Neurogenic low back pain, Spinal stenosis, cauda equina syndrome, spondylolisthesis, and Presence of any signs or symptoms of non-musculoskeletal pathology e.g. cancer, infection and fracture in low back and lower extremities based on paraclinical findings). Prior surgery to the lumbosacral spine. Inability to obtain prone lying. Severe malalignments in the cervical, thoracic, lumbar or pelvic region and the lower limbs. History of uncorrected vision impairment, vestibular, hearing or cognitive impairments. Leg length discrepancy which disturbs balance. Systemic diseases, such as diabetes, fibromyalgia, rheumatoid arthritis, degenerative diseases and other rheumatoid diseases. Needle phobia. Sacroiliac pain as identified with six clinical tests: compression, distraction, sacral thrust, thigh thrust, Gaenslen's and FABER's.
**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: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
All eligible chronic nonspecific low back pain patients will be randomized to an experimental group (dry needling of the lumbar multifidus muscle and standard physical therapy) and a control group (sham dry needling of the lumbar multifidus muscle and standard physical therapy) using the block balanced randomization with an allocation ratio of 1:1. Random allocation will be executed by a researcher not involved in the assessments or interventions. The random allocation method consists of four-letter blocks made of letters A and B (A letter shows dry needling and standard physical thearpy and letter B indicates sham dry needling and standard physical therapy). then, the randomization schedule will be placed in sequentially numbered opaque sealed envelopes. the treatment will be performed according to the number and letters of each envelope.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study the participants, outcome assessor and data analyzer will be blinded. A) Participants: The Participants will be blinded to which group they belong to. At the end of the study procedure, true dry needling will be performed for the participants in the control group. B) Outcome assessor: The examiner will be blinded to the grouping information and intervention procedure. C) Data analyzer: The data analyzer will be blinded to the grouping information and intervention procedure.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

### 1

**Registry name**
مرکز ثبت کارآزمائي هاي باليني ايالات متحده آمريکا
**Secondary trial Id**
NCT05100381
**Registration date**
2021-11-14, 1400/08/23

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
. Ethical committee of Iran University of Medical Sciences
**Street address**
5th floor, central committee, Iran University of Medical Sciences, Hemmat Expy.
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**Approval date**
2021-08-29, 1400/06/07
**Ethics committee reference number**
IR.IUMS.REC.1400.476

## Health conditions studied

### 1

**Description of health condition studied**
Chronic Nonspecific low back pain
**ICD-10 code**
M54.5
**ICD-10 code description**
Low back pain

## Primary outcomes

### 1

**Description**
pain intensity
**Timepoint**
before the intervention and one week after the intervention
**Method of measurement**
The 0-100 Numeric Pain Rating Scale (NPRS) will be used to evaluate changing in level of pain from the baseline to one week after the intervention. Zero indicates no pain and 100 indicates maximum pain that the patient experiences. The NPRS has the responsiveness to measure the level of pain in people with low back pain.

### 2

**Description**
functional disability
**Timepoint**
before the intervention and one week after the intervention
**Method of measurement**
The Persian version of The Oswestry Disability Index will be used to evaluate changing in functional disability.This questionnaire includes 10 activities of daily living and a total score of 100. A score below 25 indicates the lowest level of disability, 25 to 50 moderate disability, 50 to 75 severe disability, and 75 to 100 acute disability. The validity and the reliability of the Persian version of this questionnaire has been shown in the previous studies.

## Secondary outcomes

### 1

**Description**
postural control
**Timepoint**
before the intervention and one week after the intervention
**Method of measurement**
The force platform (Germany, Kistler, 9260AA6) will be used to evaluate postural control. Postural control will be evaluated in four different trials in double-leg stance position: 1-Eyes open on a firm surface. 2-Eyes closed on a firm surface. 3-Eyes open on a foam surface. 4-Eyes closed on a foam surface. The duration of each trial will be 90 s, three times repetition, with one minute rest interval between each trial. The variables of postural control in this investigation will be COP excursion in anteroposterior and mediolateral direction, COP amplitude Standard Deviation (dispersion) in anteroposterior and mediolateral direction and mean velocity of COP.

### 2

**Description**
pain pressure threshold
**Timepoint**
before the intervention and one week after the intervention
**Method of measurement**
The pressure algometer will be used to evaluate the Pain Pressure Threshold (PPT). The patients will be placed in a prone position and the algometer will be applied perpendicular to the muscle belly of the lumbar multifidus, approximately 1.5 cm lateral to the spinous process of the painful segments. The patients will be asked to signal verbally after perception of force change from pressure to pain. The PPT at each location will be taken three times and the mean of three repetitions will be used for statistical analysis. The validity and reliability of the pressure algometer has been shown in previous studies.

## Intervention groups

### 1

**Description**
Intervention group: The experimental group will comprise 20 participants with chronic non-specific low back pain. The treatment will include dry needling of the lumbar multifidus muscle and routine physical therapy. DRY NEEDLING METHOD: The patients will be placed in a prone position with a pillow under their belly to accommodate lumbar lordosis. Two lengths of sterile, disposable, 0.30 mm x 75 mm and 0.30 mm x 50 mm solid filament needle (Tony, China) will be used in this study. The length of the needle for each participant will be selected based on the size of the participant. The needles will be inserted into the lumbar multifidus muscle, 1.5 - 2 cm lateral to the spinous process of two or three painful segments, perpendicular to lamina (after piercing the skin, needles are directed inferomedially). 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.ROUTINE PHYSICAL THERAPY: Routine physical therapy will include low level laser therapy and motor control training. The diode laser device with 850 nm wavelength, 800 milliwatt power, pulse wave with 80% duty cycle and an average energy density of 50 J/cm2 will be utilized for the treatment procedure. The laser will be applied 1.5 to 2 cm lateral to the L1-L5 spinous process, each point for 1 minute and a total of 10 minutes. Motor control training consists of three stages of exercises. First stage exercises include abdominal drawing, abdominal bracing

and alternative arm and leg lift. Second stage exercises include unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up and sit back. Third stage exercises 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 repeat 10 times and each repetition will last 10 seconds and there will be one minute rest between each exercise. The treatment will last 3 weeks, 6 sessions, twice a week.

**Category**

Rehabilitation

**2**

**Description**

Control group: The control group will comprise 20 participants with chronic non-specific low back pain. The treatment will include "sham" dry needling of the lumbar multifidus muscle and routine physical therapy. The sham dry needling method consists of the insertion of the needles subcutaneously and no local twitch response will be obtained. The needles will be left in the place for 20 minutes. Routine physical therapy will include low level laser therapy and motor control training. Routine physical therapy will include low level laser therapy and motor control training. The diode laser device with 850 nm wavelength, 800 milliwatt power, pulse wave with 80% duty cycle and an average energy density of 50 J/cm2 will be utilized for the treatment procedure. The laser will be applied 1.5 to 2 cm lateral to the L1-L5 spinous process, each point for 1 minute and a total of 10 minutes. Motor control training consists of three stages of exercises. First stage exercises include abdominal drawing, abdominal bracing and alternative arm and leg lift. Second stage exercises include unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up and sit back. Third stage exercises 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 repeat 10 times and each repetition will last 10 seconds and there will be one minute rest between each exercise. The treatment will last 3 weeks, 6 sessions, twice a week.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

School of rehabilitation, Iran University of Medical Sciences

**Full name of responsible person**

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## Sponsors / Funding sources

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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**

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**Latest degree**

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**Other areas of specialty/work**
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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**