

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of dry needling compared to sham dry needling on the sensitization of the nervous system at peripheral, spinal and cerebral levels in patients with Non-specific Chronic Low Back Pain(NSCLBP)

#### Protocol summary

##### Study aim

Dry needling is standardly a short-term treatment and the main aim of the study is to distinguish the real effect of dry needling on sensitization and its comprehensive effect on three levels with its placebo effect.

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 56 patients. randomization was done randomizer software.

##### Settings and conduct

In this study, patients aged 18-45 years with a diagnosis of chronic non-specific back pain who referred to orthopedic clinics under the supervision of Shiraz University of Medical Sciences will be selected and will be randomly divided into two intervention and control groups. needling and the control group will receive dry needling. The following study will be conducted in the laboratory of the Faculty of Rehabilitation. The participants do not know about their therapy group and the therapist and the person doing the assessment are different people.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with non-specific chronic low back pain with a central sensitization inventory score above 40 in the age group of 18-45 years will be included in the study. To enter the study, patients must have 3-7 trigger points in the gluteal, multifidus, paravertebral, quadratus lumborum and piriformis muscles. Exclusion criteria: Patients with blood coagulation diseases, fear of needles, pregnancy, lymphedema disorders, arthritis symptoms, or slipping and fractures in vertebrae will not be included in the study.

##### Intervention groups

The intervention group received dry needling technique and the control group received sham dry needling.

##### Main outcome variables

Sensitization of the nervous system in three peripheral, spinal and brain levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230205057336N2**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

##### Registration date

2023-09-27, 1402/07/05

##### Registrant information

##### Name

Narges Meftahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 1552

##### Email address

meftahin@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-01, 1402/07/09

##### Expected recruitment end date

2024-04-02, 1403/01/14

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of dry needling compared to sham dry needling on the sensitization of the nervous system at peripheral, spinal and cerebral levels in patients with Non-specific Chronic Low Back Pain(NSCLBP)

**Public title**  
Investigating the effect of dry needling compared to sham dry needling on the sensitization of the nervous system at peripheral, spinal and cerebral levels in patients with Non-specific Chronic Low Back Pain(NSCLBP)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
At least three months have passed since the onset of their back pain Have an average age of 18-45 years There are no signs of involvement of nerve roots, disc inflammation and sciatic nerve Have at least 3 to a maximum of 7 active trigger points in the gluteus maximus, gluteus medius, quadratus lumborum, paravertebral and multifidus muscles The score of the CSI questionnaire is equal to or greater than 40 Numerical evaluation of pain should have at least score of 3 No previous history of dry needling treatment  
**Exclusion criteria:**  
History of hemophilia and coagulation disorders A patient with lymphedema Pregnancy Cancer, fracture, infection or immunodeficiency diseases such as AIDS and hepatitis Specific back pains including back pains originating from disc involvement and nerve roots, spondylolisthesis and spondylolysis A patient with back pain that is the origin of visceral pain Use of anticoagulants Patients with fear of needles in the form of phobia

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **56**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are randomly assigned to intervention and sham groups by permutation randomization method which is

done with the help of randomization program (block number 14 and block size 4). Allocation of samples is done in a ratio of 1:1. In order to hide the allocation, opaque and sealed envelopes are used.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to blind the study, evaluation tests are performed by one physiotherapist and dry needling treatment techniques are performed by another physiotherapist. Statistical analysis is performed by a person who does not know the grouping of patients. On the other hand, the participants do not know about the group they are randomly placed in.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee in Shiraz Faculty of Rehabilitation Science research

**Street address**

Abiverdi st 1, Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7194733669

**Approval date**

2023-07-26, 1402/05/04

**Ethics committee reference number**

IR.SUMS.REHAB.REC.1402.016

**Health conditions studied**

**1**

**Description of health condition studied**

Non-specific Chronic Low Back Pain

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Conditioned pain modulation

**Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

The difference in pressure pain tolerance threshold with algometer before and after the application of conditioned pain by pressure cuff

## **2**

### **Description**

Temporal summation of pain

### **Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

The difference in pain report based on numeric rate scale after one stimulation and several repeated painful stimulations

## **3**

### **Description**

Pressure pain threshold both in the pain area and in the distal area

### **Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

Record the number shown on the algometer display at the moment of pain after applying pressure

## **4**

### **Description**

Central sensitization

### **Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

Central sensitization inventory

## **Secondary outcomes**

## **1**

### **Description**

Pain

### **Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

Numeric rate scale

## **2**

### **Description**

Function rate

### **Timepoint**

Before, immediately and six weeks after the intervention

### **Method of measurement**

Extensor muscle endurance test

## **Intervention groups**

## **1**

### **Description**

Intervention group: Patients in this group receives three

treatment sessions with an interval of 72 hours. In the range of minimum 3 to maximum 7 muscles from lumbar multifidus muscles, gluteus maximus, gluteus medius, quadratus lumborum and paravertebral muscles, which is considered as paravertebral muscle, lumbar iliocostalis muscle. All muscles are selected and dry needled based on the number of active trigger points they have. In this dry needling study, the fast in-fast out technique is used. We manipulate the needle in different directions until the first twitch is seen. The size of the needles is selected according to the volume of fat tissue in the patient's body. In cases where it is necessary, strong pressure is applied to compress the skin tissue.

### **Category**

Treatment - Other

## **2**

### **Description**

Control group: Control group: the needle is taken out of the box without tearing its packaging, and its tip is shortened enough that it no longer touches the patient's skin and is placed back in the packaging. The patient is placed exactly like the treatment group for all muscles and an alcohol pad is used. In this treatment, the guide is pressed on the patient's body to create a sensation similar to dry needling. Other interventions will be completely similar to the intervention group.

### **Category**

Placebo

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Shiraz Medical Sciences Rehabilitation Center

#### **Full name of responsible person**

Narges meftahi

#### **Street address**

Abiverdi 1 st, Chamran Blvd

#### **City**

Shiraz

#### **Province**

Fars

#### **Postal code**

7194733669

#### **Phone**

+98 71 3627 1552

#### **Email**

meftahin@sums.ac.ir

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Shiraz University of Medical Sciences

#### **Full name of responsible person**

Narges Meftahi

**Street address**

Abiverdi st, Chamran Blvd

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**Email**

meftahin@sums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Narges Meftahi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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7194733669

**Phone**

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**Email**

meftahin@sums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Narges meftahi

**Position**

Asistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Narges Meftahi

**Position**

Asistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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