Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 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 lumbarum, 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 lumbarum 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Narges Meftahi

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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
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Person responsible for updating data

Contact

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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