

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Ultrasonographic evaluation thickness of Multifidus muscles before and immediately after dry needling in non- specific low back pain patients in comparison sham group

Protocol summary

Study aim

Investigating the effect of dry needles in the pattern of muscle activity of multifidus in patients with chronic non-specific low back pain

Design

Clinical trial, parallel group, double blind, non-randomized

Settings and conduct

after completing the consent form and demographic characteristics in the neuromuscular Rehabilitation Research Center, participants were included. the thickness of the multifidus is measured by ultrasonography in rest and contraction at first, then needle therapy is performed in prone in the 1.5 cm spinous process is inclined to the muscles at a 20 ° angle with internal and lower orientation. In this study, participants are blinded to type of intervention (real-sham needle therapy) And the main investigator are blind to the type of intervention of each participants

Participants/Inclusion and exclusion criteria

inclusion criteria: age between 18 and 45; have back pain for three months ago or more; Pain in the region between the margin of the costa up to the top of the lower fold of the gluteal; pain intensity below 3 based on visual pain scale; exclusion criteria: any symptoms of serious spinal cord involvement; symptoms of Spinal Cord Syndrome; Symptoms of Spinal Cord Stenosis; symptoms of Nerve root involvement; spinal manipulation , stabilization exercises in Multifidus lumbar during the last 4 weeks; any signs and symptoms of a pathology (cancer, infection, etc.); history of any problems with coagulation or taking anti-clot drugs; pregnancy; fear of needle

Intervention groups

dry needle group: insertion of needle in lumbar multifidus, one session for 5 seconds at each trigger point sham group: without insertion of needle(Contact

needles on the skin)

Main outcome variables

Thickness of multifidus in rest; thickness of multifidus in submaximal contraction mode; Percentage changes in thickness of multifidus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043012N1**

Registration date: **2019-06-18, 1398/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-18, 1398/03/28**

Update count: **0**

Registration date

2019-06-18, 1398/03/28

Registrant information

Name

pooran madani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-22, 1398/02/02

Expected recruitment end date

2019-07-24, 1398/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ultrasonographic evaluation thickness of Multifidus muscles before and immediately after dry needling in non- specific low back pain patients in comparison sham group

Public title

assessment the thickness of multifidus muscles activity before and after one session dry needling in patient with low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 45 years Having back pain for a period of three months ago or more Pain in the region between the margin of the costa up to the top of the lower fold of the gluteal region Pain intensity below 3 based on visual pain scale

Exclusion criteria:

Any symptoms of serious spinal cord involvement Symptoms of cauda equina Syndrome Symptoms of spinal canal stenosis Symptoms of Nerve root involvement Spinal manipulation Fear of the needle stabilization exercise in the lumbar multifidus muscles during the last 4 weeks any signs and symptoms of a pathology (cancer, infection, etc.) history of any coagulation problems or taking anti-clot drugs pregnancy

AgeFrom **18 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **20****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Participants are blind to the type of intervention, that way in sham group, the needle is moved only on the skin and the needle does not actually enter the multifidus.the main investigator is blind to the type of intervention of each participant, so that main investigator uses the assistant to intervene

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

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Tabatabaee clinic, Mashahir square, Blvd ghods

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35196-98375

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.SEMUMS.REC.1397. 272

Health conditions studied**1****Description of health condition studied**

Non-specific chronic low back pain

ICD-10 code

M95-M99

ICD-10 code description

Other disorders of the musculoskeletal system and connective tissue

Primary outcomes**1****Description**

Lumbar Multifidus muscle rest thickness

Timepoint

Measuring the thickness of the multifidus Before,immediately after and 10 days after the end of intervention

Method of measurement

ultrasonography setting

2**Description**

Thickness of submaximal contraction mode of the lumbar Multifidus muscle

Timepoint

Measuring the thickness of the multifidus Before,immediately after and 10 days after the end of intervention

Method of measurement

ultrasonography setting

3

Description

Muscle thickness changes of lumbar Multifidus

Timepoint

Measurement of thickness changes of the multifidus
Before, immediately after and 10 days after end the
intervention

Method of measurement

ultrasonography setting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group: non-specific low back pain volunteers, with real dry needle therapy. In this one session technique, needles with sizes 0.30 ~ 50 mm or 0.30 ~ 60 mm are used according to the size of the muscle participant. In this technique, the patient is lying down and inserted the sterile needle into the muscle of the multifidus at the L4-L5 or L5-S1 levels. needle is placed approximately 1.5 cm next to spinous proces vertically at the desired surface. After punching the surface of the skin, the needle toward the multifidus and lumbar vertebral lamina.oriented downward and inward (approximately 20 °).

Category

Treatment - Devices

2

Description

Control group: nonspecific low back pain volunteers without insertion of needle(sham).In this technique, like intervention group, the patient is prone and the needle contacts the skin without insert to the muscle.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic Taba Babaei

Full name of responsible person

pooran madani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Pooran Madani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

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

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available