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 multiphidus 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 ultra sonography 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

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

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target 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
Street address
Tabatabaee clinic, Mashahir square, Blvd ghods
City
semnan
Province
Semnan
Postal code
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 updating data

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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