Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of the effect of conventional physiotherapy and conventional physiotherapy with lumbar multifidus dry needling on pain, disability and pressure pain threshold in patients with chronic non specific low back pain

Protocol summary

Study aim

Study the effect of conventional physiotherapy and the effect of multifidus muscle dry needling with conventional physiotherapy on pain, disability and pressure pain threshold in patients with chronic non-specific low back pain

Design

A randomized clinical trial with controlled, paralleled groups, double blind with a sample size of 40 people

Settings and conduct

After the call, people with chronic non-specific low back pain are randomly divided into intervention and control groups. Statistical analysts and patients are unaware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion : Back pain between the 12th rib and the buttock area , Age between 18 and 50 years, active trigger point in the lumbar multifidus muscle, At least three months of low back pain, BMI<40 kg/m2 exclusion : Rheumatic and systemic diseases,Contraindications of dry needling, fibromyalgia syndrome and neurological problems, Pregnancy, mental disorders, previous lumbar surgery, Uncontrolled endocrine disorders

Intervention groups

Control group: 20 people will be placed in this group and will receive 8 conventional physiotherapy sessions including: TENS, US and Hot pack in addition to conventional exercises. Intervention group: 20 people, similar to the control group, will receive conventional physiotherapy plus three sessions of dry needling of the multifidus muscle.

Main outcome variables

Pain, Disability , pressure pain threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210221050441N1**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Mehdi Marani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of conventional physiotherapy and conventional physiotherapy with lumbar multifidus dry needling on pain, disability and pressure pain threshold in patients with chronic non specific low back pain

Public title
Comparison of the effect of conventional physiotherapy and conventional physiotherapy with lumbar multifidus dry needling on pain, disability and pressure pain threshold in patients with chronic non specific low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Back pain between the 12th rib and the buttock area Age between 18 and 50 years active trigger point in the lumbar multifidus muscle At least three months of low back pain BMI<40 kg/m2

Exclusion criteria:
Rheumatic and systemic diseases Contraindications of dry needling such as: trauma, taking anticoagulants, infections, immune and heart diseases fibromyalgia syndrome and neurological problems Pregnancy, mental disorders, previous lumbar surgery Uncontrolled endocrine disorders

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
It is done by randomization secretary and permuted-block method with blocks of volume 4 . In this method, there are ten blocks of 4 in the form of a list, each block has 4 numbers that are randomly designed by the statistical analyzer. In each block, 2 smaller numbers are allocated to the conventional physiotherapy group and 2 larger numbers are assigned to the conventional physiotherapy group with dry needling. When referring to these groups, the samples are randomly placed from the first to the last list and two people in the intervention group and two people in the control group in each block.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the statistician, he analyzes the results without knowing the groups. To blinding patients, patient placed in the prone position and shows the patient the real needle, but when the needle is inserted, a false needle (through the tooth) is struck on the skin and after that the patient does not see the false needle.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan university of medical science

Street address
Isfahan University of Medical Sciences , Hezar Jerib street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-08-06, 1401/05/15

Ethics committee reference number
IR.MUI.NUREMA.REC.1401.057

Health conditions studied

1

Description of health condition studied
chronic non specific low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain

Timepoint
Before, after and one month after treatment

Method of measurement
Visual Analogue Scale

2

Description
Pressure pain Threshold

Timepoint

Before, after and one month after treatment

Method of measurement

Algometer

3

Description

Disability

Timepoint

Before, after and one month after treatment

Method of measurement

oswestry disability index

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 20 people are included in this group and 8 conventional physiotherapy sessions include: 20 minutes TENS, 4 minutes US and 15 minutes Hot pack, in addition conventional exercises including knee to chest , raising the trunk in prone position,heel slide in supine position , bridging and bicycle training. Each exercise will be repeated 10 times and each repetition will be done for 10 seconds.

Category

Rehabilitation

2

Description

Intervention group: 20 people are included in this group and 8 conventional physiotherapy sessions in addition dry needling of the multifidus muscle includes: 20 minutes of TENS, 4 minutes of US and 15 minutes of Hot pack, in addition conventional exercises including knee to chest , raising the trunk in prone position,heel slide in supine position , bridging and bicycle training, as well as three sessions of dry needling in the second, fourth, sixth session and inserting and removing the needle into the muscle for 10 seconds. Each exercise will be repeated 10 times and each repetition will be done for 10 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedigheh tahereh Rehabilitation center

Full name of responsible person

Hosseinali ahmadi

Street address

khorram st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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Deputy of research and technology ,Isfahan University of Medical Sciences , Hazar Jarib Street

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mojtaba Heshmatipour

Position

Associate professor

Latest degree

Master

Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

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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
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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The personal information of the persons and the results of the treatment and their relationship cannot be shared with each other, only the analyzed information without mentioning the names of the persons is accessible to other researchers.
When the data will become available and for how long
Since the publication of the results
To whom data/document is available
Researchers and other physiotherapists
Under which criteria data/document could be used
In order to access for the design of other studies by researchers and to increase the quality of treatment by colleagues and other physiotherapists
From where data/document is obtainable
Author
What processes are involved for a request to access data/document
If the request is registered in the email, it will be answered as soon as possible
Comments