Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of dry needling on pain intensity, pressure pain threshold, remote muscle performance and disability in subjects with fibromyalgia and chronic nonspecific low back pain

Protocol summary

Study aim
The purpose of this study is to investigate the effect of dry needling on pain intensity, pressure pain threshold, remote muscle performance and disability in subjects with fibromyalgia and chronic nonspecific low back pain

Design
A randomized (using block randomization method), single-blinded, clinical trial with two parallel group designs and a sample size of 30 patients

Settings and conduct
The study is performed in the rehabilitation faculty of Iran University of Medical Sciences. Then eligible participants sign an informed consent form and are randomly assigned to two groups of dry needling and control by Block balanced randomization technique. Treatment and assessment are done by separate persons and the assessor and analyzer of data will be kept blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: Fibromyalgia diagnosed The pain should be between the edge of the 12th rib and the lower gluteal fold Patients have trigger points in the multifidus, quadratus lumborum and gluteus medius muscles Exclusion criteria: Spinal and pelvic pathologies such as fracture Dry needling treatment in the last 6 months.

Intervention groups
Experiment group: Pharmacological treatment and dry needling Control group: Pharmacological treatment

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045652N7**
Registration date: **2023-03-11, 1401/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-11, 1401/12/20**
Update count: **0**

Registration date
2023-03-11, 1401/12/20

Registrant information

Name
marzieh Yassin
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of dry needling on pain intensity, pressure pain threshold, remote muscle performance and disability in subjects with fibromyalgia and chronic

nonspecific low back pain

Public title
The effect of dry needling in subjects with fibromyalgia with low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 18 to 65 Fibromyalgia diagnosed by a rheumatologist The pain should be between the edge of the 12th rib and the lower gluteal fold The duration of pain is more than three months The minimum Visual analogue scale at the time of visit should be 3 out of 10 Patients have trigger points in the multifidus, quadratus lumborum and gluteus medius muscles Have a minimum Oswestry Disability Index score of 20 out of 100 The participants should be able to understand and read Persian language in order to fill the questionnaire

Exclusion criteria:
Spinal and pelvic pathologies such as fracture, infection and tumor Presence of systemic infection Coagulation and bleeding disorders Presence of lymphedema or removal of lymph nodes pregnancy The presence of a pacemaker Severe respiratory and cardiovascular disorders epilepsy History of trauma to the lumbopelvic region History of surgery in the lumbopelvic region Lumbar radiculopathy Dry needling treatment in the last 6 months Cognitive impairment Needle phobia Uncontrolled diabetes Systemic joint disease such as rheumatoid arthritis Symptoms of radiculopathy and pressure on the nerve root Cauda equina syndrome Spondyloarthropathies Metal pins or prosthetic joints Inability to communicate with the patient

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation is done by block method, blocks of 4 letters consisting of letters A and B are randomly selected. Blocks are created by Random Number Generator and their sequence is specified. The letter A represents the intervention group and the letter B represents the control group. A random sequence of random blocks is then generated. Referral buying companies are placed in one of two intervention or control groups with the help of this random sequence. The person who generates the randomization sequence will not participate in any other phase of the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the method of blinding the examiner will be used. The examiner of the results of the study, who is a physiotherapist with a history of examination, is not aware of the allocation of groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran university of medical sciences

Street address
Iran university of medical sciences, next to Milad tower, Hemmat highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2022-10-24, 1401/08/02

Ethics committee reference number
IR.IUMS.REC.1401.610

Health conditions studied

1

Description of health condition studied
Fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

2

Description of health condition studied
Chronic Nonspecific Low Back Pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description

Pain

Timepoint

The first session before treatment, the fourth session before the start of the treatment, the sixth session before the start of the treatment, one month after the last treatment session, three months after the last treatment session

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Muscle performance

Timepoint

The first session before treatment, the sixth session before the start of the treatment, one month after the last treatment session

Method of measurement

dynamometer and Isometric test of neck flexor muscles

2

Description

Pressure pain threshold

Timepoint

The first session before treatment, the sixth session before the start of the treatment, one month after the last treatment session

Method of measurement

Algometer

3

Description

Functional disability

Timepoint

The first session before treatment, the sixth session before the start of the treatment, one month after the last treatment session

Method of measurement

Oswestry disability index

4

Description

Central sensitization

Timepoint

The first session before treatment, the sixth session before the start of the treatment, one month after the last treatment session

Method of measurement

fibromyalgia 2011 questionnaire, Algometer

Intervention groups

1

Description

Intervention group: Performing dry needling technique for lumbar multifidus, quadratus lumborum and gluteus medius. In order to apply dry needling to the lumbar multifidus muscle, the patient is placed in the prone position. The muscle is palpated flat next to the vertebral spines (about one centimeter outside the spines). This area is considered as a safe area for dry needling the multifidus muscle when the needle is applied in this area and inward and downward towards the lamina of the vertebra. Based on the size of the patient, a 40 or 50 mm needle is used. To apply dry needling to the quadratus lumborum muscle, the patient lies on the side of the non-involved side. Lumbar spine, twelfth rib and iliac crest are identified. The needle is applied from the outer side of the transverse process of the lumbar vertebrae directly down, and in order to avoid the risk of damage to the kidney, we will not go higher than the level of the transverse appendage of the second lumbar vertebra. Generally, a needle with a length of 50 to 60 mm is suitable. Also, in order to apply dry needling to the gluteus medius muscle, the patient lies in the prone position and the muscle is needled with a flat touch along the iliac crest. The tissue is pressed to reduce the distance between the skin and the desired muscle. The size of the needle varies based on the amount of fat tissue present. In fact, in the middle third of the distance between the upper anterior articular spine and the upper posterior articular spine is the needle application area. The examiner first washes his hands with soap and after drying them uses sterile latex gloves. According to the recommendation of the National Acupuncture Foundation, before applying the needles, the surface of the patient's skin will be disinfected with 70% isopropyl alcohol. The needles used are sterile and disposable and their size is selected according to the size of the patient, the target muscle and the desired penetration depth. The needles are TONY brand made in China. The dry needling technique is performed by a physiotherapist who has an official dry needling certificate from the Iranian Physiotherapy Association. The dry needling method in this study will be based on the method provided by César Fernández-de-las-Peñas Jan Dommerholt. The needles are applied in order to obtain a local contraction response and this process continues until no more local contraction occurs. Finally, the needles are removed from the tissue and the position is cleaned again with cotton soaked in alcohol

Category

Rehabilitation

2

Description

Control group: Patients in both groups will receive Pharmacotherapy under the supervision of a rheumatologist, and people in the experimental group will also receive dry needling intervention. For ethical considerations, after completing the plan and measuring the results, the patients in the control group will also receive dry needling

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy clinic of Rehabilitation Faculty of Iran University of Medical Sciences

Full name of responsible person
Marzieh Yassin

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Masoume Matin

Position
Student

Latest degree
Bachelor

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