# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

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Tehran

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Tehran

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**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**
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## Sponsors / Funding sources

**1**

**Sponsor**

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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**
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**Position**
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**Latest degree**
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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