# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of adding paraspinal lumbar muscle dry Needling technique to the general postural reeducation approach of patients with non-specific chronic low back pain

## Protocol summary

**Study aim**
Comparative evaluation of the effects of paraspinal muscles dry needling against the GPR (General Postural Retraining) approach in patients with non-specific chronic low back pain

**Design**
This study is a clinical trial including control and intervention groups with parallel, double-blind groups on 40 patients, who will be randomly divided into two groups.

**Settings and conduct**
This study will be performed in a private clinic in Tehran, Iran. In intervention group, 10 GPR sessions will be performed every other day in combination to 5 dry needling sessions. In the control group, 10 GPR sessions will be performed every other day.

**Participants/Inclusion and exclusion criteria**
Inclusion: People with low back pain who are in the age range of 25 to 50 years Pain more than 3 base on Visual Analogue Scale (VAS) Disability score of at least 25 Non-specific low back pain for three months or more Results of the below test should be positive: Anterior and posterior pelvic tilt Prone hip extension test Side lying hip abduction test Thomas test Ober test

**Intervention groups**
In this study, both groups receive the GPR technique and in the intervention group, the dry needling technique will be added.

**Main outcome variables**
Pain, function, flexibility.

## General information

**Reason for update**

**Acronym**
GPR

**IRCT registration information**
IRCT registration number: **IRCT20211123053161N1**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

**Registration date**
2022-01-03, 1400/10/13

**Registrant information**

**Name**
Naeimeh Alimardani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 21 4460 8378

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-11-20, 1400/08/29

**Expected recruitment end date**
2022-02-04, 1400/11/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of adding paraspinal lumbar muscle dry Needling technique to the general postural reeducation approach of patients with non-specific chronic low back

pain

**Public title**
adding paraspinal lumbar muscle dry Needling technique to the general postural reeducation approach of patients with non-specific chronic low back pain
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Existence of pain based on visual analog scale more than 3 and 4 Disability score of at least 25 Low Back Pain for more than three months without specific cause Positive tests of muscle Imbalance
**Exclusion criteria:**
Neurological, Rheumatic, or oncological problems They received physiotherapy less than 6 months ago Did not take the corticosteroids or oral medications Those who had needling phobia Osteoporosis Systemic disease such as arthritis The history of pelvic and lumbar surgery during the last six months Pregnancy No muscle imbalance
**Age**
From **25 years** old to **50 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The allocation of individuals to the two groups will be by random allocation. Block randomization will be used. The therapist divides people into subgroups called blocks. 8 to four blocks are selected. Individuals in each block are randomly divided into two groups: control (A) and treatment (B). We have 40 per in block each group 20 per in intervention group and 20 per in control group to do this, excel computer software is used.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The blinding of this study will be double-blind. In other words, people enter the study randomly and in the grouping, neither the people themselves know which group they are in nor the person who does the evaluation.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
The way of grouping in this study is that both control and intervention groups receive a basic treatment (general postural retraining), but in the intervention group, in addition to the basic treatment, dry needle treatment will be performed for them.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of the University of Social Welfare and Rehabilitation Sciences
**Street address**
Daneshjoo Blvd., Koodkiar Alley, University of Social Welfare and Rehabilitation Sciences
**City**
Tehran
**Province**
Tehran
**Postal code**
14731-19373
**Approval date**
2021-11-20, 1400/08/29
**Ethics committee reference number**
IR.USWR.REC.1400.208

## Health conditions studied

### 1

**Description of health condition studied**
Non-Specific chronic low back pain
**ICD-10 code**
M95.9
**ICD-10 code description**
Acquired deformity of musculoskeletal system, unspecified

## Primary outcomes

### 1

**Description**
1-Pain
**Timepoint**
Before, after and 2 weeks follow up
**Method of measurement**
Visual analog scale

### 2

**Description**
2- Function
**Timepoint**
Before, after and 2 weeks follow up
**Method of measurement**
Ostwersy disability index

**3**

**Description**
Flexibility level
**Timepoint**
Before, after and 2 weeks follow up
**Method of measurement**
Finger to floor test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Treatment in this group includes 10 sessions GPR with one day interval (three times in a week) plus 5 sessions of dry needling.
**Category**
Treatment - Devices

**2**

**Description**
Control group: In this group, only ten GPR sessions are given every other day.
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Private physiotherapy clinic
**Full name of responsible person**
Naeimeh Alimardani
**Street address**
South Janatabad St., Chahar Bagh Square, Green Building, First Floor, Unit 12
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
University of social welfare and rehabilitation sciences
**Full name of responsible person**
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webmaster@uswr.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
University of social welfare and rehabilitation 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**
University of social welfare and rehabilitation sciences
**Full name of responsible person**
Naeimeh Alimardani
**Position**
Master student
**Latest degree**
Master
**Other areas of specialty/work**
Physiotherapy
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Some of the data, such as information about the consequences, can be shared.

**When the data will become available and for how long**
Starting the access period: 6 months after publition the results.

**To whom data/document is available**
Researchers working in academic and academic institutions.

**Under which criteria data/document could be used**
Only statistical analyzes can be used to find treatment for improvement of patients.

**From where data/document is obtainable**
Applicants can be guided by email authors.

**What processes are involved for a request to access data/document**
First, they will email the authors of the study and we Will be answered within a week.

**Comments**