

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

#### Protocol summary

##### Study aim

Comparison of the therapeutic effect of traditional acupuncture with trigger point acupuncture in patients with low back pain

##### Design

Clinical trial with control group, with parallel groups will be done on 48 patients.

##### Settings and conduct

In this study, patients are divided into three groups: trigger point acupuncture, traditional acupuncture and control group. In each group, 16 patients with low back pain are referred to one of the medical centers of Shafaiehian or Firoozgar.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria (patients who presented with pain in the lumbar region): Patients should be in the age range of 18 to 60 years. All patients should have at least one active trigger point. Besides, the patients' vas number should be more than 4. Exclusion criteria: Pregnancy, neuromuscular junction disorders, neurological defects found on electromyography, progressive neurological defects, urinary or fecal incontinence following pain, Progressive decrease in muscle strength, radicular pain, orthopedic disorders of the lumbar region, or history of lumbar surgery Rheumatologic disorders, a diagnosed history of hip and sacroiliac joint problems, known psychological disorders, or cancer.

##### Intervention groups

1st intervention group: trigger point acupuncture group, the treatment is performed in trigger points for up to 6 sessions, Once every two days, for 12 days. 2nd intervention group: traditional acupuncture group, the treatment, and points are determined based on the principles of Chinese medicine and meridian lines, which will be done for up to 6 sessions, Once every two days, for 12 days. Control group: patients will have only standard low back pain exercise and NSAID use.

##### Main outcome variables

Pain, disability, kinesiophobia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201207049636N1**

Registration date: **2021-04-23, 1400/02/03**

Registration timing: **prospective**

Last update: **2021-04-23, 1400/02/03**

Update count: **0**

##### Registration date

2021-04-23, 1400/02/03

##### Registrant information

##### Name

Fatemeh sadat Taghizadeh mayani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8848 1704

##### Email address

taghizadehf892@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-05, 1400/02/15

##### Expected recruitment end date

2021-11-22, 1400/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

#### Public title

Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Of the patients who presented with complaints of low back pain, 48 patients were studied. Patients should be in the age range of 18 to 60 years. All patients should have at least one active trigger point. Patients must have a vas (visual analog scale) score more than 4.

##### Exclusion criteria:

Pregnancy Neuromuscular junction disorders Neurological defects found in electromyography Progressive neurological defects Urinary or fecal incontinence following pain Progressive decrease in muscle strength Lumbar orthopedic disorders or a history of lumbar surgery Rheumatologic disorders Diagnosed history of hip and sacroiliac joint problems Known psychological disorders Cancer

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **48**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

48 identical envelopes are prepared for randomization, The name of the intervention (types of intervention) is evenly placed in each envelope (16 envelopes per intervention). After closing the envelopes, the envelopes are shuffled so that the sequence of interventions is not clear. Each participant randomly selects one of the envelopes And after opening the envelope, the examiner will perform the type of treatment based on the treatment in the envelope.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### 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, Hemmat Highway next to Milad Tower, Tehran.

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2020-11-04, 1399/08/14

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.532

### Health conditions studied

### 1

#### Description of health condition studied

low back pain

#### ICD-10 code

M54.5

#### ICD-10 code description

Low back pain

### Primary outcomes

### 1

#### Description

Pain reported by the patient in the vas questionnaire

#### Timepoint

The beginning of the intervention, one week, one month and three months later

#### Method of measurement

Vas pain measurement questionnaire

### Secondary outcomes

### 1

#### Description

Patient's disability based on Oswestry Disability Index (ODI) questionnaire

#### Timepoint

The beginning of the intervention, one week, one month and three months later

#### Method of measurement

ODI Disability Questionnaire

### 2

#### Description

kinesiophobia

#### Timepoint

The beginning of the intervention, one week, one month

and three months later

#### **Method of measurement**

kinesiophobia TSK (Tampa Scale of Kinesiophobia)  
Questionnaire

## **Intervention groups**

### **1**

#### **Description**

1st Intervention group: In the trigger point acupuncture group, the treatment will be performed for up to 6 sessions, Once every two days, for 12 days with disposable dong-bang needles of stainless steel in the size of 0.25 × 0.4. After sterilizing with alcohol, the needle enters into the painful points, which are called trigger points. The needles are inserted by the guide tube in the marked painful points and the insertion depth of the needles is 15 to 30 mm. Which remain in place for 20 minutes per session, while at the 10th minute the needles are rotated for re-stimulation.

#### **Category**

Treatment - Other

### **2**

#### **Description**

2nd Intervention group: In the traditional acupuncture group, treatment is done for up to 6 sessions, Once every two days, for 12 days and points have been determined based on the principles of Chinese medicine and meridian lines that these points in low back pain will include BL20-BL23-ST40-BL63-SP3-SP10-LIV6-P6-P7. In these patients, disposable Dong-Bang stainless steel needles in the size of 0.25 × 0.4 are inserted after sterilizing the points with alcohol cotton by the guide tube. The insertion depth of the needles is 15-30 mm and remains for twenty minutes. The needles in the traditional acupuncture group must be rotated and manipulated in place to achieve a feeling of numbness and heaviness or temporary burning at the site, which is called de qi sensation.

#### **Category**

Treatment - Other

### **3**

#### **Description**

Control group: In the control group, patients will have only standard low back pain exercise and NSAID use.

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Firoozgar hospital

##### **Full name of responsible person**

Korosh Mansori

#### **Street address**

Firoozgar Hospital, Beh Afarin St., Karim Khan St.,  
Valiasr Sq., Tehran.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۵۹۳۷۴۷۸۱۱

#### **Phone**

+98 21 8214 1809

#### **Email**

h\_firoozgar@yahoo.com

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Shafayehiaian hospital

##### **Full name of responsible person**

Korosh Mansori

##### **Street address**

Shafayehiaian Educational and Medical  
Center, Mojahedin-e-Islam St., Baharestan  
Square, Tehran.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1157637131

##### **Phone**

+98 21 3848 7000

##### **Email**

PR@iums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Seyyed Abbas Motavalian

##### **Street address**

5th floor, head quarters, Iran University of Medical  
Sciences, Hemmat Highway next to Milad Tower,  
Tehran.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1449614555

##### **Phone**

+98 21 8214 1229

##### **Email**

amotevalian@yahoo.com

#### **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**

Korosh Mansori

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Iran University of Medical Sciences, Hemmat Highway  
next to Milad Tower, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Phone**

+98 21 8214 1600

**Email**

mansori.k@iums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Korosh Mansori

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Email**

mansori.k@iums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Korosh Mansori

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Phone**

+98 21 8214 1600

**Email**

mansori.k@iums.ac.ir

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Table of data obtained from the mentioned  
questionnaires

**When the data will become available and for how long**

Access period starts 6 months after the results are  
published

**To whom data/document is available**

It will be available only to researchers working in  
academic and scientific institutions

**Under which criteria data/document could be used**

The use of documents is allowed only by mentioning the source.

**From where data/document is obtainable**

Dr. Kourosh Mansouri, Department of Physical Medicine and Rehabilitation, Shafaiehian Hospital, Baharestan Square, Tehran, 09156538667,

taghizadehf892@gmail.com.

**What processes are involved for a request to access data/document**

The data is provided to the individual as soon as it is authenticated.

**Comments**