

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of vagues nerve stimulation on lumbopelvic myofascial pain syndrome with chronic functional constipation

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of articular branch of vagus nerve stimulation on pain, trigger point sensitivity, constipation symptoms and autonomic function in patients with lumbopelvic myofascial pain syndrome with chronic functional constipation

##### Design

A randomized, blinded and sham controlled clinical trial with a parallel group. based on block randomization, 40 participants will be placed in one of the groups, and the blocks will be randomized.

##### Settings and conduct

People with informed consent and blinded to the intervention (10 sessions of vagus nerve stimulation) will participate in this study, which is conducted in a physical therapy clinic. The participants will be assessed for the presence of trigger points (algometer), constipation (Rome IV criteria), widespread pain (widespread pain syndrome index). The pain pressure threshold, VAS, quality of life and heart rate variability will be evaluated before and after treatment.

##### Participants/Inclusion and exclusion criteria

People between 20 and 50 years who have functional constipation, chronic widespread pain and trigger points in at least 3 muscles of the lumbopelvic muscles are included in the study. People with cardiovascular, neurological, thyroid, inflammatory, malignant, psychotic diseases and during pregnancy or menopause are excluded.

##### Intervention groups

All Patients will receive 10 sessions in the 4-week treatment. The auricular vagal nerve stimulation will be applied to left ear (the concha part) for 30 minutes, using a biphasic waveform (250  $\mu$ s, 25Hz). In the placebo group, the protocol will be the same as the intervention group, only the stimulation will be applied to the ear lobe.

##### Main outcome variables

constipation symptoms; pain intensity; pressure pain threshold; heart rate variability; quality of life; anxiety level

#### General information

##### Reason for update

Delay in start of sampling and starting treatment

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221231056994N1**

Registration date: **2023-01-29, 1401/11/09**

Registration timing: **prospective**

Last update: **2023-04-21, 1402/02/01**

Update count: **1**

##### Registration date

2023-01-29, 1401/11/09

##### Registrant information

###### Name

Fariba Khosravi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-08-22, 1403/06/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of vagus nerve stimulation on lumbopelvic myofascial pain syndrome with chronic functional constipation

**Public title**

Effect of vagus nerve stimulation on lumbopelvic pain with constipation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Body mass index less than 30 kg/m<sup>2</sup> Having at least two signs of the Rome IV criteria The presence of trigger points in at least 3 muscles from the rectus abdominus, psoas major, iliacus, quadratus lumborum, piriformis, obturator internus, hamstrings, tensor fascia lata, adductors, gluteus medius, gluteus minimus, gluteus maximus and coccygeus on each side using algometer widespread pain index is equal to or greater than 7

**Exclusion criteria:**

Neurological diseases Metabolic and endocrine diseases Thyroid diseases Infectious and inflammatory diseases Myopathy diseases Cardiovascular diseases Systemic diseases such as scleroderma and lupus Cognitive and psychotic diseases Surgeries of the digestive system Long-term use of corticosteroids Addiction and alcohol consumption Taking drugs that affect the autonomic system (such as cholinergic and anticholinergic drugs and alpha and beta blockers) Pregnancy and menopause History of malignancy Hemorrhoid, fissure and grade 3 and 4 rectal prolapse diseases

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization is done individually in a sealed envelope. In this two-group trial study, 20 participants are in the intervention group and 20 participants are in the placebo group. With two groups, 5 blocks are created, with 8 people in each block (4 participants in the intervention group and 4 participants in the placebo group). The size of the blocks is equal. A lottery is drawn between the blocks, and people are randomly placed in the blocks based on this lottery. This method aims to balance the number of samples allocated to each of the groups. People take out cards with random sequence and

even numbers (intervention group) and odd numbers (placebo group) written on them from the envelope (The cards are inside sealed envelopes, the contents of the envelopes are not clear). In order to maintain the random sequence, the numbering on the envelopes is done in the same order and the lid of the envelopes is glued and placed inside a box. It should be noted that the random sequence of cards and the allocation of participants to treatment groups are not done by one person so that the randomization process is done correctly.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participants are blinded that the stimulation is done in the ear region in both groups, only in the placebo group the stimulation is in the earlobe so the subjects do not know which group they are in. Also, in order to prevent the interference of information, it is determined randomly from among the days of the week which of the two groups will be assigned to each day.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

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kodakyar Ave., daneshjo Blvd.,Evin

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**Postal code**

1985713871

**Approval date**

2023-01-18, 1401/10/28

**Ethics committee reference number**

IR.USWR.REC.1401.205

**Health conditions studied****1****Description of health condition studied**

lumbopelvic myofascial pain syndrome

**ICD-10 code**

G89.29

**ICD-10 code description**

Other chronic pain

## 2

### **Description of health condition studied**

chronic functional constipation

### **ICD-10 code**

K59.0

### **ICD-10 code description**

Constipation

## **Primary outcomes**

### 1

#### **Description**

The complete spontaneous bowel movements per week

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

The number of times a person has bowel movements per week

## **Secondary outcomes**

### 1

#### **Description**

Heart rate variability

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

PowerLab data acquisition

### 2

#### **Description**

Quality of Life scale

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

Patient Assessment of Constipation Quality of Life questionnaire

### 3

#### **Description**

Beck anxiety level

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

Beck Anxiety Inventory

### 4

#### **Description**

pain pressure threshold

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

Algometer

### 5

#### **Description**

Pain intensity

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

Visual Analogue Scale

### 6

#### **Description**

Severity constipation

#### **Timepoint**

Before and after 10 sessions of treatment

#### **Method of measurement**

Wexner questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients are placed in a room with a temperature of  $25 \pm 2$  degrees in a supine position. In this study, the electroacupuncture is used to stimulate the afferents of auricular branch of vagus nerve in the concha region of the left ear. For this purpose, a continuous two-phase current with a pulse width of 250 microseconds and a frequency of 25 Hz is applied for 30 minutes. In this study, needle are used, which are placed in the mentioned area after cleaning the skin with an alcohol swab. Participants familiarize with the stimulus for 1 minute before starting the therapeutic technique, and then the intensity is slowly increased until it reaches the desired intensity. The stimulation amplitude is adjusted individually before each session to achieve a tingling sensation. This sensation should not be painful to selectively stimulate the A $\beta$  afferent fibers of the vagus nerve. It should be noted that treatment is performed in 10 sessions, one day apart.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Patients are placed in a room with a temperature of  $25 \pm 2$  degrees in a supine position. In this study, the electroacupuncture is used to stimulate the left earlobe. For this purpose, a continuous two-phase current with a pulse width of 250 microseconds and a frequency of 25 Hz is applied for 30 minutes. In this study, needle are used, which are placed in the mentioned area after cleaning the skin with an alcohol swab. Participants familiarize with the stimulus for 1 minute before starting the therapeutic technique, and then the intensity is slowly increased until the current is felt very little. It should be noted that since there is no treatment in the placebo group, people who are randomly placed in this group will receive 10 free physiotherapy sessions after the completion of the course.

#### **Category**

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Gandom physiotherapy clinic

**Full name of responsible person**

Zahra Amiri - Fariba Khosravi

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Health medical Buildings, the First south, Alley 2,  
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**Email**

f.khosravi280@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Dr. Hamidreza Khankeh

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kodakyar Ave., daneshjo Blvd.,Evin

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**Web page address****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**

10

**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**

Fariba Khosravi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

#### Contact

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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**

A code is considered for each person, and based on this code, the data related to the variables for each person can be shared after making them unidentifiable.

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

The access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

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

If it is necessary to carry out more statistical analyzes or to report other results in addition to the obtained results. the names of the executive agents should be mentioned when reporting the results.

**From where data/document is obtainable**

Fariba Khosravi 09131985863 F.khosravi280@gmail.com

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

The person announces his request through email or phone number. Documents will be provided at most one month after the announcement of the request.

**Comments**

The applicant is required to keep the information confidential.