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 µs, 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 vagues nerve stimulation on lumbopelvic myofascial pain syndrome with chronic functional constipation

Public title
Effect of vagues nerve stimulation on lumbopelvic pain with constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index less than 30 kg/m2 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 lumbarum, 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
Street address
kodakyar Ave., daneshjo Blvd.,Evin
City
Kerman
Province
Tehran
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±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 Aβ 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±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, Esteghlal St.
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Email
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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
Dr. Hamidreza Khankeh
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kodakyar Ave., daneshjo Blvd.,Evin
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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
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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No 3, First floor, East 6, Alley 12, Gohary street, Shahab Ave
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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.