Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of percutaneous auricular vagus nerve stimulation in chronic widespread myofascial low back and cervical pain syndrome

Protocol summary

Study aim

Investigation the effectiveness of percutaneous auricular vagus nerve stimulation in chronic widespread myofascial pain syndrome

Design

A block randomised, sham controlled clinical trial with blinded outcome assessment with a parallel group design of of 68 patients

Settings and conduct

68 patients with diagnosed chronic widespread low back and cervical myofascial pain syndrome are randomly (block randomization) divided into 2 groups. The intervention group is assigned 10 sessions of percutaneous auricular vagus nerve stimulation, while the control group receive shame therapy in private physiotherapy clinics in Kerman. Patients take out the sealed envelopes so the assigned group of that participant is determined. Patients were assessed before and after the 10 sessions using the Visual Analog Scale (VAS) for pain, and also assessed for the presence of trigger points in more prevalent pain sites for each muscle. The outcome measurements included a heart rate variability (HRV) and pressure pain threshold (PPT), Low Back Pain Disability, Neck Disability, Kinesiophobia , Anxiety

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients in the age range of 25-55 years 2. Having the criteria of lumbar and neck myofascial syndromes based on the criteria provided by Travell and Simon 3- The patient should have pain for at least 3 months. 4- Causing pain of at least 3 out of 10 on the visual scale Exclusion criteria: 1. Neurological, Metabolic and endocrine, Inflammatory and Systemic diseases 2. History of malignancy 3. Pregnancy and Menopause 4. Use of painkillers in the last 24 hours 5. Cardiovascular diseases 6. Taking drugs that affect the autonomic system,

Intervention groups

In the treatment group, auricular vagus nerve stimulation is performed in Cymba Concha. In the control group, stimulation in earlobe.

Main outcome variables

pain; pain pressure threshold; disability

General information

Reason for update

Change the sample size during the sampling process, to increase statistical power and reduce random error, as well as based on a review of other literature, we increased the sample size to 34 participants in each group. This adjustment was made prior to conducting the main statistical analyses and without consideration of preliminary results. Approval for this sample size increase was obtained from the Graduate studies Office of the University of University of Social Welfare and Rehabilitation Sciences as well as from the Ethics Committee.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056989N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **prospective**

Last update: **2025-06-11, 1404/03/21**
Update count: **2**

Registration date

2023-01-30, 1401/11/10

Registrant information

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Mahboobeh Abdolalizadeh

Name of organization / entity

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2024-03-18, 1402/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of percutaneous auricular vagus nerve stimulation in chronic widespread myofascial low back and cervical pain syndrome

Public title
Effects of percutaneous auricular vagus nerve stimulation in chronic widespread myofascial pain syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients in age 25 to 55 years Body mass index less than 30 kg/m2 Having the criteria of lumbar and neck myofascial syndromes based on the criteria provided by Travell and Simon in the muscles of the back and neck the patient have pain for at least 3 months. The presence of at least 3 trigger points in the muscles of the back and neck, where one of these two areas involves the muscles bilaterally (by using an algometer, as well as by touch) Intensity of pain of at least 3 out of 10 on the Visual Analog Scale (VAS) Patients whose Wide Spread Pain Index (WPI) is equal to or greater than 7
Exclusion criteria:
Neurological diseases Metabolic and endocrine diseases Systemic diseases such as lupus, scleroderma Infectious diseases Inflammatory diseases Thyroid diseases History of malignancy Diabetes Pregnancy Menopause Use of painkillers in the last 24 hours Long-term use of corticosteroids Drug addiction Cognitive and psychotic diseases Myopathies Cardiovascular diseases Taking drugs that affect the autonomic system, such as cholinergic and anticholinergic drugs, alpha and beta blockers, antipsychotics
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two intervention groups (vagus nerve stimulation) and sham group (placebo vagus nerve stimulation) by block randomization. 34 patients are in the intervention group and 34 patients are in the placebo group. 17 blocks are created and there are 4 patients in each block. (2 patients are in the intervention group and 2 patients are in the sham group). The size of the blocks is equal. Election by lots is used between the blocks and people are randomly placed in the blocks based on this election. This method aims to balance the number of samples allocated to each group. People take out the cards that have a random sequence and the letters A (intervention group) and B (placebo group) are written on them from the box (the cards are inside the envelopes, the contents of the envelopes are not clear).In this way, the assigned group of that patient is determined. In order to maintain a random sequence, the envelopes are numbered in the same order. It should be noted that the random sequence of cards and the allocation of patients to treatment groups are not done by one person so that the randomization process is done correctly. In order to prevent the interference of information, the days of the treatment sessions during the week for each group is determined randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are randomly divided into two groups. intervention groups: vagus nerve stimulation and sham group (placebo vagus nerve stimulation). Electrical stimulation is performed in both groups. In the intervention group, electrical stimulation is performed at the distribution site of the vagus nerve (concha and simba conca area of the ear), but in the placebo group, stimulation is applied at the earlobe, which is not the distribution site of the vagus nerve. Therefore, in this way, patients do not know that they are belong to which group. In order to prevent the interference of information, the days of treatment sessions during the week for each groups is determined randomly (even or odd days).
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, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran Post code: : 1985713871

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2023-01-18, 1401/10/28

Ethics committee reference number
IR.USWR.REC.1401.206

Health conditions studied

1

Description of health condition studied
Chronic Widespread Myofascial Low Back and Cervical Pain Syndrome

ICD-10 code
G89.4

ICD-10 code description
Chronic pain syndrome

Primary outcomes

1

Description
Heart Rate Variability (HRV)

Timepoint
Before and after 10 sessions

Method of measurement
PowerLab data acquisition system

Secondary outcomes

1

Description
Low Back Pain Disability

Timepoint
Before and after 10 sessions

Method of measurement
Oswestry Low Back Pain Disability (ODI)

2

Description
Low Back Pain Diability

Timepoint
Before and after 10 sessions

Method of measurement
Roland-Morris Disability Questionnaire (RMQ)

3

Description
Neck Disability

Timepoint
Before and after 10 sessions

Method of measurement
Neck Disability Index (NDI)

4

Description
Kinesiophobia

Timepoint
Before and after 10 sessions

Method of measurement
Tampa Scale of Kinesiophobia (TSK)

5

Description
Anxiety

Timepoint
Before and after 10 sessions

Method of measurement
Beck Anxiety Inventory (BAI)

6

Description
Heart Rate Variability

Timepoint
Before and after 10 sessions

Method of measurement
PowerLab data acquisition system

7

Description
Pain Pressure Threshold (PPT)

Timepoint
before and after 10 sessions

Method of measurement
algometer

8

Description
Pain

Timepoint
before and after 10 sessions

Method of measurement
Visual Analog Scale (VAS)

Intervention groups

1

Description
Intervention group: The intervention group is assigned 10 sessions of percutaneous auricular vagus nerve stimulation (biphasic rectangular with 250 microseconds pulse and 25 Hz) is applied for 30 minutes in conchae and cymba conchae area of ear (site of distribution of the auricular vagus nerve). Shame group: 10 sessions stimulation in earlobe (biphasic rectangular with 250 microseconds pulse and 25 Hz) which is not the site of distribution of the vagus nerve.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pooyesh Physiotherapy Clinic
Full name of responsible person
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Pooyesh Phisiotherapy Clinic, Nikan Building, between 8th and 10th alley, Jahad Blvd, kerman, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Mahboobeh Abdolalizadeh
Position
PhD student of Physical Therapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
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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 patient and the data related to variables, primary and secondary outcomes for each patient are entered based on that code and these data can be shared.

When the data will become available and for how long
Up to one year after the publication of the study results

To whom data/document is available
Our data will be available to researchers in academic and scientific institutions

Under which criteria data/document could be used
If it is necessary to perform more statistical analyses on the data or to obtain results other than ours, the data will be accessible.

From where data/document is obtainable
Mahboobeh Abdolalizadeh, Gmail: mahabd55@gmail.com, Tel: 00989133409234

What processes are involved for a request to access data/document
The applicant submits his/her request via email or phone, and the information and data will be provided to them within 2 weeks after the call.

Comments
The applicant should comply confidentiality rules.