Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of simultaneous pressure of Shenmen ear and Neiguan points on anxiety and physiological indicators of patients with exacerbated COPD referred to the Emergency department

Protocol summary

Study aim
Determining the effect of simultaneous pressure of Shenmen ear and Neiguan points on anxiety and physiological indicators of patients with exacerbated COPD referred to the Emergency department

Design
A double-blind clinical trial with a sham group. Allocation of samples in groups is done randomly and using permutation blocks on 90 patients.

Settings and conduct
The study will be conducted in the emergency department of Bohlol Gonabad and Imam Hasan Bojnurd hospitals. First, all patient's physiological and anxiety indicators will be measured and recorded. Then the intervention will be carried out, and 20 minutes later, the physiological and anxiety indicators will be measured again. This study is double-blind in that the samples and the person evaluating the variables will not know how the samples are allocated to the intervention and sham groups.

Participants/Inclusion and exclusion criteria
Patients with exacerbated COPD referred to the emergency department of Bahlul Gonabad and Imam Hassan Bejnoord Hospitals who were included in the study according to the inclusion criteria.

Intervention groups
For intervention, gentle and simultaneous pressure will be applied on the Shenmen point of the ear and the Nigwan point of the non-dominant hand in a rotating manner with an average of 20-25 cycles per minute and counter-clockwise for 10 minutes and only once; In the sham group, acupressure will be applied to false points.

Main outcome variables
Anxiety; Physiological indicators

General information

Reason for update

Acronym
COPD

IRCT registration information
IRCT registration number: **IRCT20231231060580N1**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information

Name
Mahsa Khani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-10, 1403/04/20

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of simultaneous pressure of Shenmen ear and Neiguan points on anxiety and physiological indicators of patients with exacerbated COPD referred to the Emergency department

Public title
The effect of simultaneous pressure of Shenmen ear and Neiguan points on anxiety and physiological indicators of patients with exacerbated COPD

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic obstructive pulmonary disease stage II , III and IV Based on the GOLD guideline (Global Initiative for Chronic Obstructive Lung Disease) No change in medication in the 3 months before the start of the study Without signs of pulmonary edema Not having a history of heart disease, kidney failure, thyroid dysfunction, body dysfunction, cancer according to oneself No history of receiving acupressure Not taking any sedative and anti-drugs and medicine Sufficient alertness to answer questions (GCS>13) Informed consent to participate in the study Absence of local problems in acupressure points Absence of speech, hearing or mental problems that hinder communication Not having a history of diagnosed mental disorder according to his own statement

Exclusion criteria:
Occurrence of unstable hemodynamic conditions and clinical malaise Refusing to continue participating in the study during the implementation of the intervention

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description of each method: simple randomization, permutation blocks Sampling will be done in an available manner and based on the entry criteria. Then they will be randomly assigned to sham and intervention groups using four permutation blocks (AABB, ABAB, ABBA, BABA, BAAB, BBAA) by throwing a dice. In this way, we give codes 1 to 6 to each quadruple permutation block to match the numbers in the dice. We give AABB code 1, ABAB block code 2, ABBA block code 3, BABA block code 4, BBAA block code 5, and BAAB block code 6. Then, because the required sample size for this research is 90 people, we have to throw the dice 23 times (4*12=48) so that at least 90 samples are included in the study, and after matching the number of the dice with the code belonging to the replacement blocks, We line up the order of samples one after the other. In this method, the letters A mean the samples placed in the intervention group, and the letters B mean the samples placed in the sham group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind in that the samples and the researcher who evaluates the level of anxiety and physiological indicators will not know about the allocation of the samples in the intervention and sham groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Dr. Mehdizadeh Blvd, Nurse St, Gonabad

City
Gonabad

Province
North Khorasan

Postal code
9691793718

Approval date
2024-03-12, 1402/12/22

Ethics committee reference number
IR.GMU.REC.1403.002

Health conditions studied

1

Description of health condition studied
Anxiety of patients with chronic obstructive pulmonary disease

ICD-10 code
J00-J99

ICD-10 code description
بیماری های دستگاه تنفس

Primary outcomes

1

Description
Anxiety
Timepoint
Measurement of anxiety before the start of the intervention and 20 minutes after the end of the intervention
Method of measurement
Spielberger questionnaire

Secondary outcomes

1

Description
Physiological indicators
Timepoint
Measurement of physiological indicators before the start of the intervention and 20 minutes after the end of the intervention
Method of measurement
Physiological indicators registration

Intervention groups

1

Description
Intervention group: Intervention group: gentle and simultaneous pressure will be applied on the sand point of the ear and the Nigwan point of the non-dominant hand with an average of 20-25 cycles per minute and counter-clockwise for 10 minutes and only once. sham group: acupressure on false points, which will include the beginning of the ear cavity on the non-dominant side and 2.5 cm below the nigoan point of the non-dominant hand (toward the arm); will be applied.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hassan Bojnurd Hospital
Full name of responsible person
Mahsa Khani
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No. 12,Haqiqat Alley, Mazhani street, Esteghlal Blvd, Bojnurd Town
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2

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Sponsors / Funding sources

1

Sponsor
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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Mahsa Khani
Position
Master of Science in Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable