Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effect of percutaneous electrical nerve stimulation on the respiratory outcomes of patients with Covid-19 with moderate pulmonary involvement: A clinical trial

Protocol summary

Study aim
Determining the effect of percutaneous electrical nerve stimulation on respiratory outcomes in patients with Covid-19

Design
A clinical trial with a control group, with parallel groups, three-way, randomized, on 84 patients. For randomization, the 4-block method was used using software.

Settings and conduct
Participants in the study are selected from all patients in the wards of Imam Hossein Hospital in Shahroud. After random assignment of patients with two intervention and control groups, the intervention is performed in such a way that two electrodes are placed on both sides of the spinal cord of the 7-neck vertebra, and in the control group, the electrodes are placed on non-acupuncture points. Breathing (anterior to the chest) is connected and flow is established. Participants, data collectors and statistical analysts were also blinded to the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with Covid-19 with moderate pulmonary involvement Non-entry or exclusion criteria: Addiction, heart disease, liver, respiratory, kidney and advanced cancer, history of allergies and skin lesions and obesity and prohibition to be in a semi-sitting position

Intervention groups
In the intervention group, the patient is placed in a sitting or semi-sitting position, two plastic electrodes of 5 * 5 cm and adhesive are placed on both sides of the spinal appendage of the 7-neck vertebra; The electrodes are connected to NOVIN701P PLUS-STIMULATOR device made in Iran and serial number AX212088 and the frequency is set to 4 Hz and the pulse is set to 200 MICROSEC with a duration of 45 minutes. In the control group, the electrodes of the device are connected to the non-respiratory acupuncture points (anterior of the chest) and the current is established in the same way.

Main outcome variables
Respiratory consequences

General information

Reason for update
Change in sample size and update the realized sampling time The order of study outcomes also changed according to the importance of the outcomes observed during the implementation of the intervention and updated treatment protocols. In addition, the quality of shortness of breath was eliminated due to overlap with other outcomes and the large number of questions asked of the patient, leading to fatigue.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210406050871N1**
Registration date: **2021-04-25, 1400/02/05**
Registration timing: **prospective**

Last update: **2022-07-06, 1401/04/15**
Update count: **1**

Registration date
2021-04-25, 1400/02/05

Registrant information

Name
Amin Shahdad

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
2021-04-30, 1400/02/10

Expected recruitment end date
2021-08-01, 1400/05/10

Actual recruitment start date
2021-06-01, 1400/03/11

Actual recruitment end date
2021-09-30, 1400/07/08

Trial completion date
empty

Scientific title
The effect of percutaneous electrical nerve stimulation on the respiratory outcomes of patients with Covid-19 with moderate pulmonary involvement: A clinical trial

Public title
The effect of percutaneous electrical nerve stimulation on the respiratory outcomes of patients with Covid-19 with moderate pulmonary involvement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of Covid-19 diagnosis based on PCR test results or CT Scan findings (Ground Glass view) by physician Age over 18 and under 70 years Use the same treatment protocol for patients Existence of moderate pulmonary involvement (SpO2 between 90 to 93% and pulmonary involvement less than 50%) and the patient being in the second phase of Covid-19 disease according to the guideline of the Ministry of Health

Exclusion criteria:
Drug addiction Cigarette addiction Advanced metastatic cancer Congestive heart failure (grades 3 and 4) Kidney failure requires dialysis History of mechanical ventilation before intervention Existence of cardiac pacemaker Cardiac conduction disorders History of allergies and skin sensitivities in the area of the electrodes The presence of a skin lesion in the area where the electrodes are placed Hospitalized patients with other clinical manifestations of Covid-19 and no pulmonary involvement Continuous use of bronchodilators Having liver failure Moderate to severe scoliosis Obesity (BMI above 35) Psychological illnesses lead to lack of patient cooperation Cerebrovascular disorders Having COPD Having uncontrolled diabetes Inability and prohibition to be in a semi-sitting position for any reason

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Actual sample size reached: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
The 4-block block randomization method is used to create a random allocation sequence in this study because the participants gradually enter the study and also the number of assignments to each group is equal. In this research, the random allocation sequence is obtained by the methodology consultant with the software. After creating a random sequence, 84 opaque envelopes with wrappers are prepared and each random sequence is recorded on a card and placed inside the envelopes and closed. In order to maintain the sequence and to prevent disruption, the envelopes will be numbered and placed in a box. Eligible participants will be registered by the principal investigator in the order of their arrival, and an envelope will be opened in the order in which the person enters the study, one of the envelopes will be opened, and thus his / her assigned group will be revealed. Individuals will be placed equally in each group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The present study is three-blind and in addition to the participants, the data collector (outcome assessor) and the statistical analyst are not aware of the allocation of groups. The data collector who is involved in collecting and recording information such as respiration rate, pulse, oxygen saturation, etc., or in completing questionnaires will be unaware of the group of individuals. The analyst will also be unaware of the group of people. It should be noted that the physiotherapist who is responsible for the intervention and is known as the caregiver, by contacting the research colleague who has the sequence, becomes aware of the group to which each person is assigned and performs the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
7th Tir Square, Shahroud University of Medical

Sciences
City
Shahroud
Province
Semnan
Postal code
3616718473
Approval date
2021-04-11, 1400/01/22
Ethics committee reference number
IR.SHMU.REC.1400.008

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
Coronavirus disease (COVID-19)

Primary outcomes

1

Description
Percentage of arterial blood oxygen saturation
Timepoint
Daily for up to 4 days before and after the intervention
Method of measurement
Finger pulse oximeter device and monitor

2

Description
need for mechanical ventilation
Timepoint
4, 8 and 12 days after the intervention
Method of measurement
Checklist

3

Description
Death and survival
Timepoint
until the end of hospitalization
Method of measurement
Checklist

4

Description
vital signs (RR,HR)
Timepoint
Daily for up to 4 days before and after the intervention
Method of measurement
Count the respiratory rate and heart rate in a minute and record them in a checklist

5

Description
Severity of breathing (Dyspnea)
Timepoint
Daily for up to 4 days before and after the intervention
Method of measurement
Visual Analogue scale for dyspnea (VASD)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: is performed by a researcher who does not know the assignment of groups under the supervision of an Acu-TENS trained physiotherapist for the intervention group in such a way that the patient is in a sitting or semi-sitting position and by re-controlling the skin of the area for lesions, Two plastic electrodes 5 × 5 cm and sticky are placed on both sides of the spine appendage of 7 cervical vertebrae; The electrodes are connected to NOVIN701P PLUS-STIMULATOR device made in Iran and serial number AX212088 and the frequency is set to 4 Hz and the pulse is set to 200 MICROSEC with a duration of 45 minutes.
Category
Treatment - Devices

2

Description
Control group: by a researcher who does not know the assignment of groups under the supervision of a trained physiotherapist, ineffective Acu-TENS was performed for the control group in such a way that the patient is placed in a sitting or semi-sitting position and by re-controlling, the skin of in view of the lesion, two plastic electrodes of 5* 5 cm and adhesive are placed in an ineffective point for breathing, the front of the chest; The electrodes are connected to NOVIN701P PLUS-STIMULATOR device made in Iran and serial number AX212088 and the frequency is set to 4 Hz and the pulse is set to 200 MICROSEC with a duration of 45 minutes.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
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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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Mahboobeh Khajeh
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Amin Shahdad
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Latest degree
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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
Only part of the data, such as information about the main outcome, can be shared.
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
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
If necessary, contact Dr. Mahboobeh Khajeh and if there is a reasonable justification for use in scientific purposes
From where data/document is obtainable
Dr. Mahboobeh Khajeh Shahroud, 7thTir Square, Shahroud University of Medical Sciences; School of Nursing and Midwifery 02332395054 m_khajeh@ymail.com
What processes are involved for a request to access data/document
By phone call or by email and registration of the request and stating the reason and purpose of the logical and approved up to two weeks
Comments