

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 Shahrud. 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 Shahrud University of Medical Sciences

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7th Tir Square, Shahrud University of Medical

Sciences

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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

Mahboobeh Khajeh

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1

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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
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Full name of responsible person

Mahboobeh Khajeh
Position
Assistant professor
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Fax**Email**

Amin.shahdad2019@gmail.com

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 Shahrud, 7th Tir Square, Shahrud 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