# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## The effect of ear acupressure (Auriculotherapy) on Persistent Fatigue in patients recovered from the acute phase of COVID-19 disease

## Protocol summary

**Study aim**
Determining the effect of ear acupressure (Auriculotherapy) on Persistent Fatigue in patients recovered from the acute phase of COVID-19 disease Kashan, 2022

**Design**
A clinical trial study with control group with parallel groups, double-blind, randomized, on 52 patients, for block randomization of Sealed Envelope Ltd. software. 2017 available through www.sealedenvelope.com, a total of 11 blocks, 7 blocks of 4 and 4 blocks of 6, were defined.

**Settings and conduct**
After completing the course of auriculotherapy for 4 weeks on eligible clients (randomized intervention and control groups) in Kashan public and private clinics, Chalder chronic fatigue questionnaire is completed by the participants.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria are; Get a minimum score of 4 from the Chalder Fatigue Scale with bimodal scoring ,At least 6 weeks have passed since the onset of symptoms Based on the record. treatment and discontinuation, only by the doctor's order, Having a positive PCR for Covid-19 Exclusion criteria are; Re-hospitalization during the period of covid disease, Suffering from known underlying diseases, Suffering from covid complications such as thromboembolism, Connecting to a ventilator during hospitalization, Using acupuncture and acupressure within the last 3 months, taking medication, Consumption of cigarettes, alcohol or drugs

**Intervention groups**
In the auriculotherapy intervention group, Vaccaria seeds are glued on 6 points of the ear that are related to chronic fatigue and are pressed by the patient for four weeks, five days a week, twice a day and 60 times each time. In the comparison group, only the label without seeds is pasted on the points and no pressure will be applied on the points.

**Main outcome variables**
Persistent Fatigue Score

## General information

**Reason for update**
Change in sampling location due to the low number of qualified samples Sampling of outpatients in addition to hospitalized patients

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20100211003329N9**
Registration date: **2022-10-22, 1401/07/30**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **1**

**Registration date**
2022-10-22, 1401/07/30

**Registrant information**

**Name**
Zahra Sooki
**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**
2022-10-23, 1401/08/01

**Expected recruitment end date**
2023-02-20, 1401/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of ear acupressure (Auriculotherapy) on Persistent Fatigue in patients recovered from the acute phase of COVID-19 disease

**Public title**

The effect of ear acupressure (Auriculotherapy) on Persistent Fatigue in patients recovered from the acute phase of COVID-19 disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Get a minimum score of 4 from the Chalder Fatigue Scale with bimodal scoring At least 6 weeks have passed since the onset of symptoms based on the record Having a positive PCR for Covid-19 based on the record Consent to participate in the study Age range 18-65 years Iranian citizenship Resident in Kashan Body mass index less than 40 Organ health in the earlobe area Treatment and discontinuation, only with the doctor's order

**Exclusion criteria:**

Re-hospitalization during the period of covid disease Suffering from known underlying diseases (anemia, psychiatric disorders, mental retardation, thyroid disorders, multiple sclerosis, chronic heart or lung disease, cancer and hypotension, etc.) Pregnancy and breastfeeding according to patient report Suffering from covid complications such as thromboembolism based on the contents of the record Connecting to a ventilator during hospitalization based on the contents of the record Skin sensitivity to alcohol and glue according to patient report Using acupuncture and acupressure within the last 3 months taking medication Consumption of cigarettes, alcohol or drugs according to patient report

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected eligible samples will be randomly assigned to each of the two groups (intervention and control) in the form of randomization in the form of 4 and 6 blocks randomization. Using the Sealed Envelope Ltd software. 2017 Available Through www.sealedenvelope.com 7 block of 4 and 4 block of 6, overall 11 blocks were defined that the allocation to groups would be based on the order specified by the software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants and outcome assessors are unaware of the nature of the seeds pasted on participants' ears.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

**Street address**

Kashan University of Medical Sciences, Pezeshk Blvd, Qutb Rawandi Blvd, Kashan

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**Province**

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87155981151

**Approval date**

2022-09-11, 1401/06/20

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1401.114

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19

**ICD-10 code**

U09.9

**ICD-10 code description**

Post COVID-19 condition, unspecified

## Primary outcomes

### 1

**Description**

Persistent Fatigue score

**Timepoint**

Before the intervention, 4 weeks after the beginning of the intervention, 4 weeks after the end of the intervention

**Method of measurement**

Chalder Fatigue Questionnaire

## Secondary outcomes

### 1

**Description**
Allergy to seed
**Timepoint**
weekely
**Method of measurement**
Report of patient

## Intervention groups

### 1

**Description**
Intervention group: In the intervention group, the researcher will stick Seed Vaccaria brand ZHONG YANG, made in China, on 6 points related to fatigue, including: Nervous Subcortex, Sympathetic Point, Shen Men, Point Zero, Master Cerebral Point, Anti-Depressant and the patient will be taught to press the points using the thumb and forefinger for four weeks, five days a week, two times a day and 60 times each time. It should be noted that during the 4 weeks of the intervention, Vaccaria seeds will be stuck alternately on both ears by the researcher every week, after cleaning the skin with alcohol cotton. Seeds will be placed on the ears five days a week and the patient will be asked to remove the adhesives at the end of the fifth day to prevent possible allergic reaction. The patient will be instructed to contact the researcher if the adhesives are separated during the five-day period so that the researcher will stuck the adhesives in the agreed place. During the intervention, a diary sheet will be given to the person every week, in which the number of times of pressure, the occurrence of allergic reactions and taking a new drug will be specified. The contents of the daily note sheet are organized using pictorial symbols in such a way that it can be understood and completed by all samples, both literate and illiterate, with simple training. During the intervention period, every week all the participants will be visited at the agreed place and new seeds will be stuck to their ears, and a daily note sheet will be taken from them and another sheet will be given to them for the next week. If in the intervention group, the average number of daily pressures on the seeds during each week of the intervention is less than 60 times, that person will be excluded from the study. Sticking the seeds will continue for 4 weeks and the samples will be followed up 4 weeks after the end of the intervention. The 11- question form of Chalder Fatigue Score with a 4-point Likert scoring style of 0 to 3 will be completed at the beginning of the study, after the end of the intervention and 4 weeks after the end of the intervention for two groups through an interview with the individual by colleague that is not aware of assigning samples to groups. At the time of sampling, the phone number and home address of the samples will be recorded, and during the intervention period, at the end of each week, also for the purpose of follow-up 4 weeks after the end of the intervention, regarding the time and place of the visit and if necessary, the device There will be coordinated with them by phone.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: the adhesives will be stuck to the points of the Nervous Subcortex, Sympathetic Point, Shen Men, Point Zero, Master Cerebral Point, Anti-Depressant without Seed, and no pressure will be applied on them. It should be noted that during the 4 weeks of the intervention, non- seed adhesives in the control group will be glued by the researcher alternately on both ears every week after cleaning the skin with alcohol cotton. Seeds will be placed on the ears five days a week and the patient will be asked to remove the adhesives at the end of the fifth day to prevent possible allergic reaction. The patient will be taught to contact the researcher if the adhesives are detached during the five-day period so that the adhesives will be stuck by the researcher at the agreed place.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kashan public and private clinics
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## Sponsors / Funding sources

### 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**
Kashan 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**
Kashan University of Medical Sciences
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
En Not done yet
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available