Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Country
Iran (Islamic Republic of)
Phone
+98 31 5554 0021
Email address
sooki_za@kaums.ac.ir

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

City

Kashan

Province

Isfehan

Postal code

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
Full name of responsible person
zahra Tagharrobi
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5510 3119
Fax
Email
tagharrobi_z@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan

City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5510 3529
Fax
Email
hamidi_gh@kaums.ac.ir

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
Full name of responsible person
Zahra Tagharrobi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Qutb Rawandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5510 3119
Fax
+98 31 5554 6633
Email
tagharrobi_z@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zahra Tagharrobi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
City
kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5510 3119
Fax
+98 31 5554 6633
Email
tagharrobi_z@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
zahra Sooki
Position
زهرا سوکی موقعیت شغلی Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
reproductive health
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
City
kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5510 3135
Fax
+98 31 5554 6633
Email
z.sooki@yahoo.com

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