Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Effect of Acupuncture on improving the quality of smell in patients with persistent Olfactory Dysfunction after infection with the COVID-19 Virus

Protocol summary

Study aim
Investigating the impact of Acupuncture on enhancing Olfactory function in patients experiencing persistent Anosmia following COVID-19 infection.

Design
A parallel-group, single-blind, randomized controlled clinical trial was conducted with concealment of random allocation involving 60 patients.

Settings and conduct
The present study is a single-blind randomized clinical trial. The study population comprises patients referred to the ear, nose, and throat clinic of Al-Zahra and Kashani hospitals affiliated with Isfahan University of Medical Sciences who have not experienced any improvement in their sense of smell in the last month following a COVID-19 infection.

Participants/Inclusion and exclusion criteria
Patients with a confirmed diagnosis of COVID-19 in the past, who self-report experiencing Olfactory Dysfunction that has not resolved at least one month after recovery from the disease, are eligible for the study. Individuals with a history of head surgery or trauma, chronic severe Inflammatory Diseases, Degenerative Nasal Conditions, Nasal Allergies, or Abnormal Nasal Anatomy will be excluded from the study.

Intervention groups
Real Acupuncture is used in the test group. Sham Acupuncture is used in the control group.

Main outcome variables
Percentage of people with an improved sense of smell

General information

Reason for update

Acronym
COVID-19

IRCT registration information
IRCT registration number: **IRCT20110603006699N6**
Registration date: **2024-04-30, 1403/02/11**
Registration timing: **retrospective**

Last update: **2024-04-30, 1403/02/11**
Update count: **0**

Registration date
2024-04-30, 1403/02/11

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-10, 1402/02/20

Expected recruitment end date
2024-01-10, 1402/10/20

Actual recruitment start date
2023-05-10, 1402/02/20

Actual recruitment end date
2024-01-10, 1402/10/20

Trial completion date
empty

Scientific title
Investigating the Effect of Acupuncture on improving the quality of smell in patients with persistent Olfactory

Dysfunction after infection with the COVID-19 Virus

Public title
Efficacy and safety of Acupuncture in the treatment of post COVID-19 Olfactory Dysfunction
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a confirmed diagnosis of COVID-19 in the past who have self-reported Olfactory Disorders. Within a month of contracting the disease, they show no signs of recovery from their Olfactory Disorder.
Exclusion criteria:
People with a history of any Irritation or Trauma to the Head, Severe Chronic Inflammatory Diseases, Degenerative Diseases (causing Destruction or Disintegration of Nasal Mucosa), and Nasal Allergies. People with Abnormal Nasal Anatomy
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **57**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Random Allocation method will be used. Before beginning the sampling process, we will establish the Randomization sequence and then proceed with Sampling. In this scenario, we will have two vases. The first vase will contain cards numbered from 1 to 60. In vase number 2, there will be 60 non-transparent envelopes containing the desired type of treatment. First, we will randomly select a card from the first vase and an envelope from the second vase and place them in a designated box. In this way, the number removed from pot #1 will receive the treatment that is removed from pot #2. This process will be repeated for all 60 numbers. That is, we will have 60 numbers in the designated box, and each number will correspond to an envelope containing treatment. It should be noted that the type of treatment will be concealed within the envelope until the patients are assigned, and no individual will be aware of the treatment (real acupuncture or placebo acupuncture) given to the patients until their appointment. In fact, the type of intervention inside each envelope is unclear. It is uncertain whether this method involves randomization concealment. In fact, the treatment assigned to the numbers will not be known until the person visits and the envelope is opened for them.
Blinding (investigator's opinion)
Single blinded
Blinding description
In a single-blind study, participants are randomly assigned to two groups. In the first group (test group), real acupuncture is used. Sham acupuncture is used in the second group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Central Headquarters, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-05-07, 1402/02/17
Ethics committee reference number
IR.MUI.MED.REC.1402.072

Health conditions studied

1

Description of health condition studied
Olfactory Disorder
ICD-10 code
G52
ICD-10 code description
Disorders of olfactory nerve

Primary outcomes

1

Description
Percentage of people with an improved sense of Olfaction
Timepoint
Conduct an olfactory test before starting the intervention and four weeks after the intervention ends.
Method of measurement
Using a short Self-assessment of Olfactory Questionnaire (Self-MOQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After random allocation, an Olfactory test will be conducted in two sessions: the first session (before the intervention) and the second session (four weeks after the end of the intervention). In the intervention group, Real Acupuncture is utilized.
Category
Treatment - Devices

2

Description
Control group: After random allocation, an Olfactory test will be conducted in two sessions: the first session (before the intervention) and the second session (four weeks after the end of the intervention). Sham Acupuncture is used in the control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ear, Nose and Throat Clinic, Al-Zahra Hospital, Isfahan University of Medical Sciences
Full name of responsible person
Mostafa Rezaei
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2

Recruitment center
Name of recruitment center
Ear, Nose and Throat Clinic, Kashani Hospital, Isfahan University of Medical Sciences
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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Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib St.
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person

Mohammad Javad Firouz Vishkasougheh

Position
Non-faculty doctor

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available