

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

###### Name

Mehrdad Rogha

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3664 0352

###### Email address

rogha@med.mui.ac.ir

##### 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

Isfahan

##### 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

##### Street address

Soffeh Blvd, Isfahan, Isfahan Province.

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8174675731

##### Phone

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##### Email

alzahra@mui.ac.ir

##### Web page address

<https://alzahra.mui.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Ear, Nose and Throat Clinic, Kashani Hospital, Isfahan University of Medical Sciences

##### Full name of responsible person

Mojtaba Rahimi

##### Street address

Ayatollah Kashani Street, Ayatollah Kashani

Educational and Therapeutic Center, Isfahan.

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kashani@mui.ac.ir

##### Web page address

<https://kashani.mui.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

GholamReza Asgari

##### Street address

Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib St.

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##### Phone

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##### Email

research@mui.ac.ir

#### 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 Vishkasouhgh

**Position**

Non-faculty doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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Ayatollah Kashani Hospital, Isfahan.

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**Full name of responsible person**

Mehrdad Rogha

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehran Rezvani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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