

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of Auricular Acupuncture with the laser in post-viral anosmia during the COVID-19 pandemic

#### Protocol summary

##### Study aim

Determining the effect of acupuncture on olfactory quality in patients with post-viral olfactory hypersensitivity during COVID-19

##### Design

Clinical trial with a control group, single-blind, randomized using random numbers table on 90 patients

##### Settings and conduct

This study will be performed on patients with COVID-19 referred to Rasoul Akram Hospital who have not had any improvement in their sense of smell in the last 2 months. After confirmation of olfactory disorder by 24-item olfactory test and if they meet the inclusion criteria, they are randomly classified into two groups. This study is designed to be one-sided blind. As blindness will be performed on participating patients.

##### Participants/Inclusion and exclusion criteria

Patients with covid-19 who have an olfactory disorder (anosmia) and the disorder does not improve within one month of the onset of the disease are included in the study. People with a history of any surgery or head trauma, chronic and severe inflammatory diseases, degenerative diseases, nasal allergies, as well as abnormal nasal anatomy are excluded from the study.

##### Intervention groups

In the first group (experimental group) in addition to betamethasone drops, acupuncture and laser are also used. In the second group, in addition to drops and acupuncture, the laser is turned off and ear glue (placebo group) is used.

##### Main outcome variables

amount of f smell sense

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210311050671N1**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

##### Registration date

2021-04-13, 1400/01/24

##### Registrant information

###### Name

Alireza Mohebbi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6655 2828

###### Email address

mohebbi.ar@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-04, 1400/01/15

##### Expected recruitment end date

2021-07-06, 1400/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Auricular Acupuncture with the laser in post-viral anosmia during the COVID-19 pandemic

##### Public title

Evaluation of the effect of laser acupuncture on improving the sense of smell in patients with COVID-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with a definite diagnosis of Covid-19 who have reported an olfactory disorder (Anosmia) and the disorder has no improvement in their olfactory disorder within one month of the course of the disease.

**Exclusion criteria:**

People with a history of any surgery or head trauma  
Chronic and severe inflammatory diseases Degenerative diseases Nasal allergies Abnormal anatomy of the nose

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, the simple randomization method will be used. First, the randomization sequence will be determined before sampling begins, and then we will proceed to sampling. In this way we will have 2 pots. In the first pot there will be cards that will be numbered from 1 to 90, and in pot number 2, there will be 90 non-transparent envelope in which the desired treatment will be inserted. First, we will randomly select a card from the first pot and an envelope from the second pot and place them in a designed box. Thus, the number that will come out of pot number 1 will receive the treatment that will come out of pot number 2. We will do this for every 90 numbers. So, we will have 90 numbers in the box, in front of each number will be an envelope in which the treatment is placed. It should be noted that the type of treatment will be in the envelope until the patients are assigned and no one will know the type of treatment of the patients until the patient is referred. In fact, the type of intervention that exists inside each envelope is unclear, which is the randomization concealment method. In fact, the type of intervention that is inside each envelope is unclear, which is a method of concealing random allocation, in which the treatment assigned to the numbers will not be known until the person returns and the envelope is opened for her

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients will be randomly divided into two groups using a random number table. In both groups, betamethasone drops will be used. In the first group (experimental group) in addition to betamethasone drops, acupuncture and laser will also be used. In the second group, in addition to drops and acupuncture, the laser will be turned off (placebo group).

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences Shahid Hemmat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2021-03-07, 1399/12/17

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.841

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

virus identified

**Primary outcomes****1****Description**

The percentage of people with a reduced sense of smell

**Timepoint**

Perform olfactory test before the intervention, 2 weeks after the intervention and three months after the intervention

**Method of measurement**

24-item Iranian olfactory test

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Betamethasone drops, acupuncture and laser. The final follow-up of patients is 3 months after the first visit. To determine acupuncture sensitive points, both VAS (Vascular Autonomic Signal) or RAC (reflex auriculo-cardiale) method will be used both signals are the result of the micro-stress and vegetative reaction of the irradiated organism to the laser irradiation at the active points of the acupuncture. Acupuncture is performed in 2 sessions with an interval of one week and each session for 20 minutes with stimulation by IZAR laser with diode radiation source, power 400 mW, wavelength 810 and specific frequency. The screening method will be performed with 24-item Iranian olfactory test. The olfactory test will be performed in 3 sessions: the first session (before the intervention), the second session (two weeks after the intervention) and the third session (three months after the intervention).

### Category

Treatment - Other

## 2

### Description

Control group: For patients, in addition to betamethasone drops and acupuncture, laser off (placebo group) will be used.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Hazrat Rasoul AKram Hospital

#### Full name of responsible person

Alireza Mohebbi

#### Street address

Azrate Rasoule Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN

#### City

Tehran

#### Province

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#### Postal code

1445613131

#### Phone

+98 21 6650 4294

#### Fax

#### Email

mohebbi.ar@iums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

### Name of organization / entity

Iran University of Medical Sciences

### Full name of responsible person

Deputy Director of Research and Technology

### Street address

5th floor of the headquarters, Iran University of Medical Sciences, Hemmat Highway next to Milad Tower, Tehran, Iran

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Tehran

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+98 21 86709

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ivco@iums.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Alireza Mohebbi

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Ear, Nose, and Throat

#### Street address

Hazrate Rasoule Akram Hospital, Niayesh St, Satarkhan Av

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences

**Full name of responsible person**  
Alireza Mohebbi

**Position**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### 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

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Individual data of study participants will be shared after being unidentifiable.

### When the data will become available and for how long

Access period starts one year after the results are published.

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

They can compare the information of the improved people with the information of the people in their studies.

### From where data/document is obtainable

Via Email: mohebbi.ar@iums.ac.ir

### What processes are involved for a request to access data/document

An average of two weeks will take up the request to be processed.

### Comments