Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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 second 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 Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, IRAN

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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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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

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Person responsible for updating data

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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 unidentified.
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