Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessment of the effect of olfactory training on anosmia following COVID-19 infection

Protocol summary

Study aim
The effect of olfactory training on anosmia following COVID-19 infection

Design
Patients between the ages of 18-60 years following COVID-19 infection with olfactory dysfunction and a positive serology test who qualify for the study. Clinical trials are performed on all patients within a specified period of time

Settings and conduct
Patients referred to the olfactory clinic of Amir Alam Hospital in Tehran, where the severity of olfactory disorder is first assessed by SIT test. Patients are then undergo olfactory training for 3 months and then re-evaluated by SIT test.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients between 18-60 years old following COVID-19 infection with olfactory dysfunction and positive serology test Exclusion Criteria: History of head trauma, Parkinson's disease, nasal polyposis and other diseases and medications that cause olfactory disorders. Anatomical and olfactory transmission pathways detected by PNS CT scan. Negative test for anti-coronavirus serology Intolerance and poor follow-up during the trial Death of the patient for any reason

Intervention groups
Intervention group 1: Evaluation of the effectiveness of olfactory rehabilitation with different aromas as a therapeutic method and helping patients with olfactory disorders following COVID-19 Intervention group 2: Evaluation of the effectiveness of olfactory rehabilitation with different aromas as a treatment and aid to patients with olfactory disorders following COVID-19 and also comparison of the effectiveness of rehabilitation start time in patients (3 months vs. 6 months)

Main outcome variables
Improve the sense of smell and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200629047953N1**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

Registration date
2021-03-17, 1399/12/27

Registrant information

Name
Mohammadsadegh Zabihidan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3630 8353

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sina_zabihidan@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2022-03-01, 1400/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Assessment of the effect of olfactory training on anosmia following COVID-19 infection

Public title
Effect of olfactory training on anosmia of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Smell disorders caused by COVID-19 during Coronavirus pandemia Positive Serology of COVID-19
Exclusion criteria:
Diseases causing smell disorders Drugs causing smell disorders Sinonasal anatomical disorders Negative Anti-COVID antibody test
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Considering that the numbers of patients who have been suffering from olfactory disorder due to corona pandemic for 3 months and have inclusion criteria of the study, and according to statistical estimates, at least 40 patients are required, all patients who refer to the clinic are selected. First, the olfactory recognition test is tested with the smell test booklet of Danesh Bonyan Company (Iran Smell Identification Test). The initial result is recorded. Then, they will be treated by the package of Olfactrin Oral Rehabilitation Sprays for 3 months by inhaling this package twice a day. The odor test is performed again and the result is recorded. Also, the second group or the control group are patients who have had olfactory disorder for more than 6 months and no rehabilitation intervention has been performed in the last three months.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethnics committee of Tehran University of Medical Sciences
Street address
Amir A'lam Hospital, Saadi St., Darvazeh Dowlat
City
Tehran
Province
Tehran
Postal code
6511111457
Approval date
2020-10-13, 1399/07/22
Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1399.017

Health conditions studied

1

Description of health condition studied
Loss of smell, Olfactory Rehabilitation
ICD-10 code
R43.0
ICD-10 code description
Anosmia

Primary outcomes

1

Description
Score of Smell Identification Test
Timepoint
Measure theSIT test at the beginning of the study and 90 days after the onset of olfactory rehabilitation
Method of measurement
Iranian SIT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who have had an olfactory disorder for more than 3 months, are treated with Olfactrin Odor Rehabilitation Spray Package by smelling these sprays twice a day for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Patients who have had an olfactory disorder for more than 6 months, and have not undergone any rehabilitation intervention in the past three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir A'lam Hospital
Full name of responsible person
Mohammad Reza Firoozifar
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North Saadi St., Enqelab St., (Darvzeh Dowlat)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh Basti
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Phone
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Email
deanmed@tums.ac.ir
Web page address
http://medicine.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammadsadegh Zabihidan
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
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