

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Email address

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 pandemic 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**

Ethics committee of Tehran University of Medical Sciences

Street address

Amir A'lam Hospital, Saadi St., Darvazeh Dowlat

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Tehran

Province

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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 centers1**Recruitment center****Name of recruitment center**

Amir A'lam Hospital

Full name of responsible person

Mohammad Reza Firoozifar

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

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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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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