

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect and factors related to olfactory rehabilitation in patients with olfactory dysfunction after COVID-19 infection

Protocol summary

Study aim

Evaluation of the effect of Olfactrain product in olfactory rehabilitation in patients with olfactory dysfunction after Covid-19 infection

Design

A clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, phase 2-3 on 240 patients. Blocks with size of four were used for randomization.

Settings and conduct

The location of the study is the Ear, Throat, and Nose Clinic of Amir Alam Hospital. This clinic is a reference center for studies and treatment of ear, throat, and nose diseases. Blinding was not done in this study. First, patients go to the established specialist and are visited. Then, for all patients, the demographic profile, satisfaction, and smell form are filled by the clinic personnel, then, if needed, a CT scan is performed in order to check their smell problem in detail. At the beginning of the treatment, a smell identification test is performed and their scores are recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Decreased olfactory or olfactory change after Covid-19 infection At least 3 months have passed since the onset of the olfactory disorder. - 18 - age of patients between 60 Exclusion criteria: - History of head trauma or olfactory loss before Covid-19 infection - History of illness, surgery, or brain tumor

Intervention groups

Patients in the intervention group are treated for 3 months with olfactory rehabilitation with the four main scents of rose, eucalyptus, clove, and lemon. Patients in the control group are followed up for three months and after three months of waiting for olfactory rehabilitation.

Main outcome variables

Odor test score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211109053018N1**

Registration date: **2022-09-10, 1401/06/19**

Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**

Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Seyyed Behnam Abdollahi Boraei

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 4404 6347

Email address

behnam.abdollahi87@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect and factors related to olfactory rehabilitation in patients with olfactory dysfunction after COVID-19 infection

Public title

Olfactory rehabilitation by Olfactrain product

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Decreased olfactory (anosmia and hyposmia) or olfactory change (phantom or crocosmia) after Covid 19 infection (infection detection method is recorded in the data entry form) At least 3 months have passed since the onset of olfactory disorder.

Exclusion criteria:

History of head trauma or olfactory loss before Covid-19 infection History of surgery or brain tumor Patient examination or CT scan in patients is beneficial for olfactory conduction disorder History of similar treatments with olfactory training Neurodegenerative diseases that cause olfactory disorders such as Parkinson's and Levy Buddy disease

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: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization type is blocked randomization. Bloke size 4 of intervention (A) and control (B) groups defined as (AABB, ABAB, ABBA, BBAA, BABA, BAAB) are written on six cards respectively on cards 1-6, then the cards in The envelope are placed. Each time, one of the cards is randomly taken out of the envelope and put together. Finally, a random string is made from the sequence of the selected cards (in the number of the sample size), respectively, patients A and B are entered into the study until the desired sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق در پژوهش‌های زیست پزشکی بیمارستان امیر اعلم

Street address

North Saadi Street

City

Tehran

Province

Tehran

Postal code

1145765111

Approval date

2022-02-28, 1400/12/09

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1401.006

Health conditions studied

1

Description of health condition studied

Loss of sense of smell, olfactory rehabilitation

ICD-10 code

R43.0

ICD-10 code description

Anosmia

Primary outcomes

1

Description

smell test score

Timepoint

Measure the olfactory test at the beginning of the study and 90 days after

Method of measurement

Test of 24 Iranian olfactory test

Secondary outcomes

empty

Intervention groups

1

Description

Patients are randomly divided into two intervention and control groups by using a quadruple block. Patients who are in the intervention group are treated for 3 months with olfactory training with the four main scents of rose, eucalyptus, clove, and lemon. After three months after the beginning of the study, the SIT test and the quality of life are done again and the results are compared with each other.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group are followed up for three months and after three months they are expected to have olfactory rehabilitation

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital

Full name of responsible person

Seyyed Behnam Abdollahi Boraei

Street address

Sa'adi St., Enghelab St., Amir A'lam Hospital

City

Tehran

Province

Tehran

Postal code

1439957131

Phone

+98 21 8849 7234

Email

behnam.abdollahi87@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

صندوق نوآوری و شکوفایی

Full name of responsible person

جناب آقای منصوری

Street address

No. 24, Blossoming Complex of Knowledge-Based Companies, West Zayandehrood, Pardis St., Mulla Sadra St.

City

Tehran

Province

Tehran

Postal code

1991913111

Phone

+98 21 4217 0000

Email

info@inif.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

صندوق نوآوری و شکوفایی

Proportion provided by this source

70

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Seyyed Behnam Abdollahi Boraei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

Street address

No. 146, South Gandhi St., Vanak Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1517964311

Phone

+98 21 6640 4050

Email

behnam.abdollahi87@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

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Seyyed Behnam Abdollahi Boraei

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Person responsible for updating data

Contact

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Iranian academic center for education culture and research

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Seyyed Behnam Abdollahi Boraei

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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