Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the effect and factors related to olfactory rehabilitation in patients with olfactory dysfunction afterCOVID-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

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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 afterCOVID-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

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North Saadi Street

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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
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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.
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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
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
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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