

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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

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**Postal code**

1439957131

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+98 21 8849 7234

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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**

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**Province**

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**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**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

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Assistant Professor

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## Person responsible for updating data

**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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## 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