

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

#### Protocol summary

##### Study aim

Determining the effect of olfactory training on improving the sense of smell in patients with covid 19 with olfactory disorders

##### Design

A clinical trial with a control group, with parallel groups, using a simple randomization method with closed envelopes, consisting of 50 patients in the intervention group and 50 patients in the control group. There is no blinding.

##### Settings and conduct

100 patients who have reported a disorder in the sense of smell are divided into groups by a simple random method. Both groups complete the olfactory disorders questionnaire. Then the intervention group is subjected to olfactory training with four scents of rose, eucalyptus, clove, and lemon. Olfactory training is a method in which patients perform olfactory training for 6 weeks twice a day, morning and night, each scent for 20 seconds with a 10 second interval between each scent. The control group does not perform olfactory training during this period. After 6 weeks, both groups complete the olfactory disorders questionnaire again.

##### Participants/Inclusion and exclusion criteria

The conditions for patients to enter the study are over 18 years of age and a laboratory finding of covid 19 infection, who mention olfactory disorders and do not have a history of other diseases affecting the olfactory system, as well as the use of corticosteroids.

##### Intervention groups

The intervention and control groups both complete the questionnaire. Then the patients of the intervention group undergo olfactory training for 6 weeks. The control group does not receive olfactory training during this period. Then both groups are re examined by the questionnaire and the results are compared with each other.

##### Main outcome variables

Severity of olfactory disorder in patients with covid 19,

The effect of olfactory disorder on quality of life, The effect of olfactory training on olfactory disorders caused by covid 19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220803055612N1**

Registration date: **2023-01-27, 1401/11/07**

Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**

Update count: **0**

##### Registration date

2023-01-27, 1401/11/07

##### Registrant information

##### Name

Mohammad hossein Akbarpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3528 1966

##### Email address

mh.akbarpour@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-04, 1401/11/15

##### Expected recruitment end date

2023-03-16, 1401/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

**Public title**  
Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Adult male and female (over 18 years old) who doesn't have a history of Olfactory Dysfunction before infection with Covid-19, a history of polyps in the nasal cavity, dependence on long term corticosteroids treatments for diseases such as Asthma and Chronic Obstructive Pulmonary Disease, a history of cerebrospinal fluid leakage, a history of Allergy to do not have Budesonide or other topical steroids Positive laboratory finding of Covid 19 Subjective complaint of loss of smell after infection The ability to read, write  
**Exclusion criteria:**  
patients with a history of Olfactory Dysfunction before infection with Covid 19, a history of polyps in the nasal cavity, dependence on long term corticosteroids treatments for diseases such as Asthma and Chronic Obstructive Pulmonary Disease, a history of cerebrospinal fluid leakage

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: simple randomization, randomization unit: individual, randomization tool: Excel software, how to create a random sequence: using Excel's Rand function, concealment: in order to hide the random allocation using the method of sealed non-transparent envelopes Randomized sequence waxing (SNOSE) will be used.

**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

Ethics committee of Pharmacy and Nursing and Midwifery school of Shahid Beheshti University of Medic

##### Street address

Niayesh intersection, Valiasr st.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2022-06-21, 1401/03/31

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.059

## Health conditions studied

### 1

#### Description of health condition studied

کوبید 19

#### ICD-10 code

U07.1

#### ICD-10 code description

U07.1: COVID-19, Virus identified

## Primary outcomes

### 1

#### Description

Score by Questionnaire of Olfactory Disorders - Negative Statements

#### Timepoint

Beginning and six weeks after

#### Method of measurement

Questionnaire of Olfactory Disorders - Negative Statements

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who suffer from olfactory disorders Perform olfactory training, twice a day, in the morning and at night for 6 weeks, rotating for 20

seconds each with a ten-second interval between each scent, four scents of rose, eucalyptus, and cloves. and lemon.

**Category**

Treatment - Other

**2****Description**

Control group: Patients with covid-19 and olfactory disorders do not receive any treatment.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Health deputy of Babol University of medical sciences

**Full name of responsible person**

Dr Mitra Zandi

**Street address**

Modarres

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Babol

**Province**

Mazandaran

**Postal code**

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**Phone**

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**Email**

mh.akbarpour1@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ziai

**Street address**

Shahid Chamran Highway, Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

193954719

**Phone**

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**Email**

mpd@sbm.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Akbarpour

**Position**

Msc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Pasdaran 10 st.

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4741858315

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Akbarpour

**Position**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Data on main outcomes can be shared.

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

The data will be available only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

assessment of the effectiveness of the trainings 6 months after the study

**From where data/document is obtainable**

through the email address mh.akbarpour1@gmail.com

**What processes are involved for a request to access data/document**

the answer will be given one week after the requester sends an email to the mentioned email address.

**Comments**