

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

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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

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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

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Province

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193954719

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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

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

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

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Full name of responsible person

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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