

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of olfactory training on olfactory disorders in patients with Covid-19

#### Protocol summary

##### Study aim

Effect of olfactory training (OT) on olfactory disorders in patients with covid-19

##### Design

Clinical trial with control group, with parallel groups, single-blind, non-randomized, phase 3 on 78 patients

##### Settings and conduct

In this clinical trial study, patients with a history of being infected with Covid-19 (PCR positive) referred to Beheshti Hospital's treatment center who stated that they had smell problems for at least 3 months (since the PCR positive result). Randomization will be done - patients into two intervention and control groups -. The severity of the olfactory disorder is the same in both groups. The patients of the intervention group were treated with olfactory rehabilitation sprays for 3 months in the form of sniffing 2 times a day. The patients of the control group were treated with verticosteroid nasal spray 2 times a day for 3 months. Blinding in patients, pain sprays in both groups are completely similar

##### Participants/Inclusion and exclusion criteria

The main conditions for entering the study: Patients with a history of being infected with Covid-19 (PCR positive) referring to Shahid Beheshti Health Center who have stated that they have had smell problems for at least 3 months (since the PCR positive result). The main conditions for not entering the study: Olfactory disorder caused by head trauma - History of Parkinson's and Alzheimer's Nasal polyposis Merman's rhinosinusitis History of nose surgery -Pregnancy - Other diseases and drugs that cause olfactory disorders. - History of allergic asthma

##### Intervention groups

Intervention group: Patients will be treated with Olfactrin's olfactory rehabilitation spray package for 3 months in the form of sniffing twice a day. Control group: Patients will be treated with corticosteroid nasal spray twice a day for 3 months.

##### Main outcome variables

Odor detection rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221023056273N1**

Registration date: **2023-01-02, 1401/10/12**

Registration timing: **retrospective**

Last update: **2023-01-02, 1401/10/12**

Update count: **0**

##### Registration date

2023-01-02, 1401/10/12

##### Registrant information

##### Name

Sima Kianipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5558 9399

##### Email address

sci@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-21, 1401/01/01

##### Expected recruitment end date

2023-03-03, 1401/12/12

##### Actual recruitment start date

2022-05-05, 1401/02/15

##### Actual recruitment end date

2022-07-01, 1401/04/10

##### Trial completion date

2022-10-22, 1401/07/30

### Scientific title

Effect of olfactory training on olfactory disorders in patients with Covid -19

### Public title

Effect of olfactory training on olfactory disorders caused by covid-19 disease

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with covid 19 suffering from olfactory disorder referring to medical centers in 2022 Age 20 to 50 years

#### Exclusion criteria:

Parkinson's and Alzheimer's disease Olfactory disorder caused by head trauma Nasal polyposis Chronic rhinosinusitis History of illness or nose surgery Pregnancy Other diseases and drugs that cause olfactory disorders Anatomical disorder of the olfactory transmission path detected by PNS CT scan Getting other viral and bacterial infections at the same time as covid-19 History of asthma and allergies

### Age

From **20 years** old to **50 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **66**

Actual sample size reached: **78**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In order to blind the patients, the sprays used in the two groups will be completely similar.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

### Street address

Qutb Ravandi Boulevard - Kashan University of Medical Sciences

### City

Kashan

### Province

Isfahan

### Postal code

8715981151

### Approval date

2022-02-20, 1400/12/01

### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.201

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Odor Detection Rate

#### Timepoint

Measuring the rate of olfactory recognition at the beginning of the study and three months after the intervention (receiving olfactory rehabilitation spray or nasal corticosteroid spray)

#### Method of measurement

The measurement of smell detection will be done through the Iran Smell Identification Test (Iran-SIT).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patients will be treated with Olfactrin's olfactory recovery spray package for 3 months in the form of sniffing 2 times a day.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients will be treated with corticosteroid nasal spray twice a day for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Kashan Shahid Beheshti Hospital

**Full name of responsible person**

Amirhossein Ahsani

**Street address**

Qutb Ravandi Boulevard, Shahid Beheshti Hospital

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

ahsanianiamirhossein@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamali Hamidi

**Street address**

Qutb Ravandi Blvd., University of Medical Sciences

**City**

Kashan

**Province**

Isfahan

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**Phone**

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research@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Amirhossein Ahsani

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Doctors Complex, Elahia St., Imam Hossein Square,

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Sima Kianipour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Sima Kianipour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Infectious diseases

**Street address**

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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