Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+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
Isfehan

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
Amirhosein Ahsani
Position
Consultant
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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