Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of inhaled corticosteroids in the treatment of anosmia in patients with COVID-19

Protocol summary

Study aim
Determination of the effectiveness of intranasal corticosteroids in individuals with COVID-19.

Design
Trial type: Superiority Study plan: Parallel Sample size: 70 (intervention group = 35 and control group = 35) double blindsides

Settings and conduct
The 70 SARS-COV-02 confirmed subjects who referred with the persistent (more than 30 days) olfactory dysfunction from Imam Reza, Shariati and Qaem Hospitals, Mashhad, Iran, enrolled in this clinical trial study. Patients' olfactory dysfuntion were categorized according to the 10-graded visual analogue scale (VAS), the total score ranges from 0 (worst) to 10 (best). Patients were followed up to assess olfactory function, at the first day and 7, 14, and 30 days after treatment. Patients in the intervention group received one puff of Mometasone furoate (0.05%W/V) nasal spray in each side twice daily for four weeks. Participants in the control group administered with one puff of NaCl 0.65% (Decosalin 0.65%) in each side twice a day for four weeks.

Participants/Inclusion and exclusion criteria
The 70 SARS-COV-02 confirmed subjects who referred with the persistent olfactory dysfunction were diagnosed as confirmed COVID-19 cases by positive RT-PCR or the COVID-19 IgG/IgM Rapid Test Cassette. Patients with a history of Parkinson's, Alzheimer's, asthma, allergic, nasal trauma, surgery, and who experienced olfactory loss before COVID-19 pandemic, as well as the patients who had been also co-infected with other viruses or bacteria, and patients lost to follow-up were excluded from the study. Participants who refused to participate in follow-up measurements, provide data, or give consent considered withdrawn.

Intervention groups
The intervention group received mometasone spray twice a day

Main outcome variables
The rate of improvement of olfactory dysfunction was measured by VAS test after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200522047542N1**
Registration date: **2020-08-04, 1399/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-04, 1399/05/14**
Update count: **0**

Registration date
2020-08-04, 1399/05/14

Registrant information

Name
Masoomeh Hosseinpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3842 5633

Email address
drmh2018@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-18, 1399/04/28

Expected recruitment end date
2020-09-18, 1399/06/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of inhaled corticosteroids in the treatment of anosmia in patients with COVID-19

Public title

Effect of Corton on olfactory dysfunction in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 who have been referred or admitted to Qaem, Imam Reza, or Shariati Hospital diagnosed with a protocol defined by the World Health Organization. People who have not experienced any signs of reduced sense of smell and taste for at least 2 weeks before the onset of the first manifestation of Covid-19. People who were diagnosed with hyposmia or anosmia.

Exclusion criteria:

People with certain underlying conditions (such as Parkinson's, Alzheimer's, severe nutritional disorders, acute rhinitis, acute catarrhal sinusitis, SICA syndrome (especially after radiation), nasal mucosal congestion, for example after rhinoplasty, olfactory nerve damage in trauma, etc., which are exposed to the reduction of the sense of smell independent of the coronavirus, as well as, people who experience other viral and bacterial infections simultaneously with COVID-19 People with a history of asthma and allergies are excluded Participants who refused to participate in follow-up measurements, provide data, or give consent considered withdrawn.

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Blocked Allocation Concealment: The researcher will be provided with closed envelopes, sequences produced in sealed, opaque and numbered envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

double-blinding of physician and participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics System In Biomedical Research

Street address

School of Medicine, East Door of University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-07-17, 1399/04/27

Ethics committee reference number

IR.MUMS.REC.1399.355

Health conditions studied

1

Description of health condition studied

Anosmia

ICD-10 code

R43.0

ICD-10 code description

Anosmia

Primary outcomes

1

Description

Smell Sense

Timepoint

Time intervals: one week, two weeks, and one month after the intervention

Method of measurement

By VAS test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inhaled Corticosteroid spray (0.05% Mometasone) twice daily for 4 weeks

Category
Treatment - Drugs

2

Description
Control group: sodium chloride spray (0.65%) twice daily for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Masoumeh Hosseinpour
Street address
Dr. Shariati Hospital, Torghabe Street
City
Mashhad
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Razavi Khorasan
Postal code
Phone
+98 51 3551 0010
Fax
Email
dshh.pr@mums.ac.ir
Web page address
https://shariati.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoume Hosseinpour
Street address
Imam Reza Hospital, Ibn Sina Street ,and Ghaem Hospital, Ahmadabad Street
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9176699311
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+98 51 3840 9642
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drmh2018@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Hosseinpour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Others
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Imam Reza Hospital, Ibn Sina Street ,and Ghaem Hospital, Ahmadabad Street
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
Patient's follow up data
When the data will become available and for how long
3 months after publishing the result
To whom data/document is available
Other researchers
Under which criteria data/document could be used
for other researches
From where data/document is obtainable
Dr. Mehdi Bakhshaei Dr.Masoomeh Hosseinpoor
What processes are involved for a request to access data/document
send an email and request
Comments