

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Dec 2023

### 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-2 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 dysfunction 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-2 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 Participants who refused to participate in follow-up measurements, provide data, or give consent considered withdrawn.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

**Province**

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**

Masoumeh Hosseinpour

**Street address**

Imam Reza Hospital, Ibn Sina Street ,and Ghaem Hospital, Ahmadabad Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699311

**Phone**

+98 51 3840 9642

**Email**

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

**Street address**

Imam Reza Hospital, Ibn Sina Street ,and Ghaem Hospital, Ahmadabad Street

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**Province**

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoumeh Hosseinpour

**Position**

Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### 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  
**Street address**  
Imam Reza Hospital, Ibn Sina Street ,and Ghaem  
Hospital, Ahmadabad Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9176699311  
**Phone**  
051-8409642

**Email**  
drmh2018@gmail.com

## 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.Masoumeh Hosseinpour

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

send an email and request

### Comments