

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy and safety of nasal spray of mometasone 0.05% on olfactory improvement in patients with COVID-19: A randomized, double blind clinical trial

Protocol summary

Study aim

Evaluation of olfactory symptoms improvement according to the Pennsylvania scale and VAS in intervention group vs control

Design

A randomized, double blind with control group on 60 patients will be done. Randomization based on permuted block method with 4 numbers in each block will be done.

Settings and conduct

adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria or CT scan of the lung for evidence of involvement consistent with COVID-19 and had a olfactory dysfunction (reduced or loss of smelling) for two weeks are recruited. patients according to randomized table candidate to receive nasal spray of mometasone 0.05% or sodium chloride 0.65% twice daily one puff in each nostril for one month. Physician and assessor are blinded. The patients will be evaluated based on Pennsylvania and VAS scale at baseline and one month.

Participants/Inclusion and exclusion criteria

Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria (presence of any symptoms of cough, shortness of breath, fever, and CT scan of the lung for evidence of involvement consistent with COVID-19 infection) or PCR and had a olfactory dysfunction (reduced or loss of smelling) for two weeks. Exclusion criteria: Pregnancy and lactation History of olfactory dysfunction Taking drugs that affect the olfactory disorders Corticosteroids chronic use Nasal anatomic dysfunction Existence of dry ducts or nasal bleeding Existence of herpetic lesion Dissatisfaction with participating in the study

Intervention groups

Recruited patients according to randomized table candidate to receive nasal spray of mometasone 0.05% or sodium chloride 0.65% twice daily one puff in each

nostril for one month.

Main outcome variables

Determination of efficacy and safety of nasal spray of mometasone 0.05% on Olfactory dysfunction in COVID-19 patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044429N6**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Monireh Ghazaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2021-04-18, 1400/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of nasal spray of mometasone 0.05% on olfactory improvement in patients with COVID-19: A randomized, double blind clinical trial

Public title

Nasal spray of mometasone 0.05% effects on olfactory improvement in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria (presence of any symptoms of cough, shortness of breath, fever, and CT scan of the lung for evidence of involvement consistent with COVID-19 infection) or PCR and had an olfactory dysfunction (reduced or loss of sense of smell) for two weeks

Exclusion criteria:

Pregnancy and lactation History of olfactory dysfunction Taking drugs that affect the olfactory disorders Corticosteroids chronic use Nasal anatomic dysfunction Existence of dry ducts or nasal bleeding Existence of herpetic lesion Dissatisfaction with participating in the study

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A master randomization schedule was prepared by a person not associated with the study who used permuted blocks of random numbers. The medicine bottles and identical placebo were the same regarding size and color. Randomization was incorporated in the serially numbered bottles containing drug or placebo by person not involved with the study according to random numbers. The number of the bottle corresponded with the number of the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Outcome evaluator and participant are blinded (double blind) and aware from

grouping (intervention or placebo).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

Street address

Ibn Sina Hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

4816864193

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.MAZUMS.REC.1399.877

Health conditions studied**1****Description of health condition studied**

Anosmia

ICD-10 code

R43.0

ICD-10 code description

Anosmia

Primary outcomes**1****Description**

Olfactory symptoms improvement

Timepoint

before intervention and one month later

Method of measurement

Pennsylvania score and Visual Analogue Scale

2**Description**

Safety of mometasone nasal spray

Timepoint

weekly during the study

Method of measurement

patient tolerability

Secondary outcomes

1

Description

Olfactory symptoms improvement duration

Timepoint

End of treatment

Method of measurement

Patient interview

2

Description

Determination of effective patient factors on olfactory dysfunction

Timepoint

study period

Method of measurement

patient interview

Intervention groups

1

Description

Intervention group: Mometasone nasal spray 0.05% by Sina daru pharmaceutical company as one puff every 12 hours for one month.

Category

Treatment - Drugs

2

Description

Control group: sodium chloride nasal spray 0.65% by Sina daru pharmaceutical company as one puff every 12 hour for one month.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Monireh Ghazaeian

Street address

Ibn Sina hospital, Pasdaran Blvd

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4815733971

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+98 11 3334 3011

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ghazaeianm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way

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majsaeedi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Monireh Ghazaeian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical pharmacy

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of trial including analysis data and method of the study

When the data will become available and for how long

At the time of publication, the data of the study will be available.

To whom data/document is available

academic researchers, medical team and scientific institutes

Under which criteria data/document could be used

For research and practical purposes

From where data/document is obtainable

Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences

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

The scientific responsible person of the study will reply to the request within 10 days. ghazaeianm@gmail.com

Comments