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 elevator 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
City
Sari
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4815733971
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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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4816864193
Phone
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Email
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