Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Explanation of Havay-e-Vabaie based on Iranian medicine and relation of it with epidemies. Determining the effect of the Iranian Medicine Product based on Mentha longifolia (nasal spray) on clinical and para clinical conditions of patients with COVID-19: clinical trial

Protocol summary

Study aim

Determining the effect of Mentha longifolia spray on clinical and paraclinical status of patients with COVID-19

Design

This study is a phase 1 and 2 clinical trial, randomized, and also has a control group which has been done on 60 patients. Study is not blind. The random allocation process will be done with Random allocation software.

Settings and conduct

This study is performed in Razi Hospital of Ghaemshahr city. Infection of these patients has been confirmed by an infectious disease specialist based on clinical signs and changes in lung CT scan or standard corona test (PCR). After selecting the samples with inclusion criteria, the samples will be assigned to two groups of intervention and control, using blocking. The random allocation process will be done with Random allocation software. This study is non blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who in addition to acute respiratory disease (ARI) have one or more of the following symptoms: RR> 30. PO2 <93%. Pulmonary infiltration in chest x ray. Clinical judgment of specialist physician. 2. Age range of (18-75) years of both sexes. Exclusion criteria: 1. Pregnancy and breastfeeding 2. Existence of any history of allergy to Mentha longifolia and its products 3. Inability of the patient to consume the oral form 4. The existence of any condition which prevents the patient from continuing the therapeutic intervention based on the physician's judgment

Intervention groups

Patients will be divided into two groups: intervention and control. The control group will receive the routine treatment but the intervention group would also receive Mentha longifolia spray beside the routine treatment.

Main outcome variables

Clinical manifestations (fever, cough, RR, oxygen saturation, etc.) Laboratory manifestations Radiologic signs (if repeated)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048337N1**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **retrospective**

Last update: **2022-11-29, 1401/09/08**
Update count: **0**

Registration date

2022-11-29, 1401/09/08

Registrant information

Name

mohammad Yousofpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4426

Email address

m.yousefpour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-10, 1399/04/20

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Explanation of Havay-e-Vabaie based on Iranian medicine and relation of it with epidemies. Determining the effect of the Iranian Medicine Product based on Mentha longifolia (nasal spray) on clinical and para clinical conditions of patients with COVID-19: clinical trial

Public title
The effect of Mentha longifolia spray on patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who, have one / more of the following symptoms, in addition to acute respiratory illness (ARI):•RR> 30•PO2 <93% •Pulmonary infiltration in chest x-ray •Clinical judgment of a specialist physician 2- Age range of (18-75) years of both sexes 3- patient must not have any serious simultaneous heart, lung, brain and endocrine diseases 4- The patient's ability and personal desire to fill out a personal consent form to enter the study
Exclusion criteria:
Pregnancy and breastfeeding Existence of any history of allergy to Mentha longifolia and its products patient's Inability to consume the oral form existence of any condition that prevents the continuing of the therapeutic intervention based on the physician's judgment Patient intubation Nausea and vomiting Resistant hypoxemia loss of consciousness Hemodynamic instability
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the samples with inclusion criteria, the samples will be assigned to two groups using blocking. The random allocation process will be done with Randm allocation software. For this purpose, 10 blocks will be determined with this software and the block size is six. Based on this list, these samples are assigned to each of the intervention or control groups, respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Hazrat Vali Asr Highway
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2020-05-12, 1399/02/23
Ethics committee reference number
IR.MAZUMS.REC.1399.7483

2

Ethics committee
Name of ethics committee
National Research Ethics Committee.
Street address
Qods Town
City
Tehran
Province
Tehran
Postal code
4815733971
Approval date
2020-05-12, 1399/02/23
Ethics committee reference number
IR.MAZUMS.REC.1400.680

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
Diseases of the respiratory system

Primary outcomes

1

Description
Reduction of hospitalization rate
Timepoint
Daily
Method of measurement
Patient record

2

Description
Respiratory rate
Timepoint
Daily
Method of measurement
By RR monitor or manual counting of breaths

3

Description
Oxygen saturation
Timepoint
8 am and 8 pm
Method of measurement
Pulsoximeter

Secondary outcomes

1

Description
heart rate
Timepoint
twice a day
Method of measurement
By monitor or manually

2

Description
Blood pressure measurement
Timepoint
Daily
Method of measurement
Mercury sphygmomanometer

Intervention groups

1

Description
Intervention group: included patients who have been admitted to the corona sections of Razi Hospital in Ghaemshahr with a definitive diagnosis of Covid 19. They are also eligible for inclusion in the study based on inclusion criteria. After the needed explanations by the assistant of Persian medicine or infectious disease physician assistant about the study and obtaining written consent, they enter the study and their information is recorded. In addition to routine medications, this group is also treated with Mentha longifolia spray. This spray is prepared in the Faculty of Pharmacy of Shahid Beheshti University. The product is made using a carbol with a concentration of 1.5% as a dilute gel with a pH: 6 to prevent mucosal damage. This group receives 2 puffs in each nostril, 15 minutes before breakfast and dinner, for 2 weeks in maximum. Before use, the drug must be examined and controlled in terms of microbial contamination . The prepared spray will be examined in terms of sterility in the microbiological laboratory of Shahid Beheshti School of Pharmacy.
Category
Treatment - Drugs

2

Description
Control group: includes patients who have been admitted to the corona sections of Razi Hospital in Ghaemshahr with a definitive diagnosis of Covid 19. They are also eligible for inclusion in the study based on inclusion criteria. After the needed explanations by the assistant of Persian medicine or infectious disease physician assistant about the study and obtaining written consent, they enter the study and their information is recorded. This group only receives routine medications. No intervention is made for this group. Only the necessary information will be recorded.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital of Ghaemshahr city
Full name of responsible person
Yousofpour Mohammad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi

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Web page address

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
Yousofpour Mohammad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Consultant
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Specialist
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Person responsible for updating data

Contact

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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

The items that can be shared are: The rate of reduction of patients' hospitalization Their clinical condition Their laboratory status Other related data

When the data will become available and for how long

The access period will be started 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions and industrialist can send request to receive data.

Under which criteria data/document could be used

Applicants must obtain written permission from the owners of the documents if they intend to use the documents commercially.

From where data/document is obtainable

Dr. Mohammad Yousofpour Mazandaran University of Medical Sciences Postal Code: 4815733971 Phone: 00981133044426 Fax: 00981133044426 Email: m.yousofpoor@yahoo.com

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

Sending a written request through the institution or the factory manager to the email of the first project executor Sending the necessary identification documents Checking in documents signing a memorandum of agreement Providing the required documentations to the applicant

Comments