Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the efficacy and safety of herbal Myrtus nasal spray in controlling the symptoms of patients with mild COVID-19

Protocol summary

Study aim
Investigating the efficacy and safety of herbal Myrtus nasal spray in controlling the symptoms of patients with mild COVID-19

Design
This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

Settings and conduct
Outpatients with mild Qovid-19 referred to Baqiyatallah Hospital who are eligible for the study are randomly divided into intervention and control groups and are treated.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age: equal or more than 18 years; The patient have written consciously and freely consent to participate in the study; The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19; Confirmed diagnosis of COVID-19, with RT-PCR confirmation; Less than 7 days have passed since the onset of symptoms. Exclusion criteria: History of allergy to this nasal spray ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the inpatient care; Pregnancy; Lactation.

Intervention groups
Intervention group: Myrtus nasal spray 1 puff into each nostrile every 8 hours, for 14 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus). Control group: routine treatment according to the latest national guideline for the treatment of new corona-virus

Main outcome variables
Clinical symptoms changes (dry cough, respiratory distress, fever)

General information

Reason for update
Correction of dose (from BD to TDS) and dosage form (from inhalation spray to nasal spray)

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N63**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **retrospective**

Last update: **2020-10-26, 1399/08/05**
Update count: **1**

Registration date
2020-10-22, 1399/08/01

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the efficacy and safety of herbal Myrtus

nasal spray in controlling the symptoms of patients with mild COVID-19

Public title
Investigating the efficacy and safety of Myrtus nasal spray in controlling the symptoms of patients with mild COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: equal or more than 18 years; The patient have written consciously and freely consent to participate in the study; The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19. Confirmed diagnosis of COVID-19, with RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms.

Exclusion criteria:
History of allergy to this nasal spray ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the inpatient care; Pregnancy; Lactation.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Science

Street address
Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

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Tehran

Province
Tehran

Postal code
1435916471

Approval date
2020-05-09, 1399/02/20

Ethics committee reference number
IR.BMSU.REC.1399.159

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
Covid-19

Primary outcomes

1

Description
Clinical symptoms (dry cough)

Timepoint
Baseline (before the initiation of intervention), and day 7 from the initiation

Method of measurement
Physical examination,questionnaire

2

Description
Clinical symptoms (respiratory distress)

Timepoint
Baseline (before the initiation of intervention), and day 7 from the initiation.

Method of measurement
Pulse-oxymetery device

3

Description
Clinical symptoms (fever)

Timepoint
Baseline (before the initiation of intervention), and day 7 from the initiation

Method of measurement
Thermometer

Secondary outcomes

1

Description
Side effects
Timepoint
Before the intervention initiation (baseline) and day 7
Method of measurement
Physical examination

2

Description
Need to be hospitalized
Timepoint
Before the intervention initiation (baseline) and day 7
Method of measurement
Question from the patient

3

Description
Mortality
Timepoint
Day 28 from the initiation
Method of measurement
Clinical assessment

Intervention groups

1

Description
Intervention group: Myrtus nasal spray 1 puff into each nostril every 8 hours, for 14 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus)
Category
Treatment - Drugs

2

Description
Control group: Routine treatment according to the latest national guideline for the treatment of new corona-virus.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Seyed Mohamad Javad Hosseini
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Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Mohamad Javad Hosseini
Position
Professor
Latest degree

Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

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Position
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Critical Care Pharmacotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available