

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 Covid-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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+98 21 8821 1524

Email address

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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

City

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-oxymetry 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.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri =

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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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Latest degree

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Person responsible for updating data

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Full name of responsible person

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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