

# 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)

###### Phone

+98 21 8821 1524

###### Email address

yunespanahi@bmsu.ac.ir

##### 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](http://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

##### Street address

Baqiyatallah hospital, Mollasadra St., Vanak Sq.,  
Tehran, Iran.

##### City

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##### Province

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##### Postal code

1435916471

##### Phone

+98 21 8245 5393

##### Email

dr\_mjhosseini@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Gholamhosein Alishiri =

##### Street address

Baqiyatallah University of Medical Science, south  
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,  
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##### City

Tehran

##### Province

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##### Postal code

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##### Phone

+98 21 8245 5393

##### Email

R.bmsu@yahoo.com

#### 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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**Province**

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dr\_mjhosseini@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Yunes Panahi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Critical Care Pharmacotherapy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parisa Kianpour

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmacotherapy

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Pharmacy faculty, Tehran University of medical  
science, 16-Azar St., Enghelab Sq., Tehran, Iran

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**Province**

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**Phone**

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**Email**

parisa\_kianpour@yahoo.com

**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