

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the efficacy and safety of Nivasha oral spray in controlling the symptoms of patients with COVID-19

#### Protocol summary

##### Study aim

Investigating the efficacy and safety of Nivasha oral spray in controlling the symptoms of patients with COVID-19

##### Design

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

##### Settings and conduct

Outpatients referred to Baqiyatallah Hospital at Tehran and Shahid.motahari Hospital at Isfahan who meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

##### 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 ingredients; The patient is in another clinical trial at the same time; The patient needs to be hospitalized.

##### Intervention groups

Intervention group: Nivasha oral spray 1 puff into the mouth every 6 hours, for 7 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

Applying the latest executive changes

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001165N59**

Registration date: **2020-05-27, 1399/03/07**

Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **2**

##### Registration date

2020-05-27, 1399/03/07

##### 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

2020-05-25, 1399/03/05

##### Expected recruitment end date

2020-07-26, 1399/05/05

##### Actual recruitment start date

2020-06-21, 1399/04/01

##### Actual recruitment end date

2020-09-21, 1399/06/31

##### Trial completion date

2020-09-27, 1399/07/06

##### Scientific title

Investigating the efficacy and safety of Nivasha oral spray in controlling the symptoms of patients with COVID-19

**Public title**

Investigating the efficacy and safety of Nivasha oral spray in controlling the symptoms of patients with 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 spray ingredients; The patient is in another clinical trial at the same time; The patient needs to be hospitalized; Pregnancy; Lactation.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

Actual sample size reached: **138**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block Randomization (4\*4 blocks) with random table number method is used to randomized the patients. Even numbers were considered for the intervention group and odd numbers for the control group.

**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 Baqiyatallah University of Medical Science

**Street address**

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

**City**

Tehran

**Postal code**

1435916471

**Approval date**

2020-05-23, 1399/03/03

**Ethics committee reference number**

ir.bmsu.rec.1399.021

**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**

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

**Method of measurement**

Physical examination, questionnaire

**2****Description**

Clinical symptoms (respiratory distress)

**Timepoint**

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

**Method of measurement**

Pulse-oxymetry device

**3****Description**

Clinical symptoms (fever)

**Timepoint**

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

**Method of measurement**

Thermometer

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Nivasha spray 1 puff into the mouth every 6 hours, for 7 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**

Ali Ghazivini

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8245 5393

**Email**

ghazvinia@gmail.com

### 2

#### Recruitment center

**Name of recruitment center**

Shahid Motahari Hospital

**Full name of responsible person**

Morteza Sanagouezadeh

**Street address**

In front of Fooladshahr, Zob-Ahan Highway, Isfahan.

**City**

Fooladshahr

**Province**

Isfahan

**Postal code**

1234567891

**Phone**

+98 31 5262 4141

**Email**

drsanagoo52@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Nanoalvand arad company

**Full name of responsible person**

Mehdi Ghahreman

**Street address**

No. 17, Omid dead end, Shahid Akbar Masoumzadeh Alley, Khayyam St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8183858536

**Phone**

+98 31 3263 1541

**Email**

nanoalvandarad@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Nanoalvand arad company

**Proportion provided by this source**

80

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Industry

### 2

#### Sponsor

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Gholamhossein Alishiri

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**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**

20

**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**  
Mohammad Rezapour

**Position**  
Student

**Latest degree**  
A Level or less

**Other areas of specialty/work**  
General Practitioner

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

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1435916471

**Phone**  
+98 21 8245 5393

**Email**  
drrezapourmh@gmail.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**  
Pharmacotherapy

**Street address**

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

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1435916471

**Phone**  
+98 21 8245 5393

**Email**  
Yunespanahi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Parisa Kianpour

**Position**  
Assistant

**Latest degree**  
Specialist

**Other areas of specialty/work**  
Pharmacotherapy

**Street address**  
Pharmacy faculty, Tehran University of Medical  
Science, 16-Azar St., Enghelab Sq., Tehran, Iran.

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1417614411

**Phone**  
+98 21 6695 4709

**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