

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

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1435916471

Phone

+98 21 8245 5393

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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

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1234567891

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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.

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8183858536

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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.

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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

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Parisa Kianpour

Position
Assistant

Latest degree
Specialist

Other areas of specialty/work
Pharmacotherapy

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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