Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+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-oxymetery 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.

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Tehran

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ghazvinia@gmail.com

2

Recruitment center

Name of recruitment center
Shahid Motahari Hospital

Full name of responsible person
Morteza Sanagoueizadeh

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

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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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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

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

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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
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 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