Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Investigating the efficacy of Provita Capsule in controlling the symptoms of patients with COVID-19

Protocol summary

Study aim
Investigating the efficacy of Provita Capsule in controlling symptoms in patients with COVID-19

Design
This study is a single-center, prospective, randomized, double-blinded, placebo-controlled, parallel phase 3 clinical trial.

Settings and conduct
Patients who is admitted to Baqiyatallah hospital, and is met the inclusion criteria, will be participated to the study and randomly be assigned into intervention and control group.

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 either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement,or RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms. Exclusion criteria: History of allergy to the ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Pregnancy; Lactation; Impossibility of oral nutrition;

Intervention groups
Intervention group: Provita Capsule, 1 cap., every 12 hours, for 7 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus). Control group: Placebo Capsule, 1 cap., every 12 hours, for 7 days (In addition to 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

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N60**
Registration date: **2020-05-28, 1399/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-28, 1399/03/08**
Update count: **0**

Registration date
2020-05-28, 1399/03/08

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
2020-05-14, 1399/02/25

Expected recruitment end date
2020-07-15, 1399/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the efficacy of Provita Capsule in controlling the symptoms of patients with COVID-19

Public title
Investigating the efficacy of Provita Capsule 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 either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement,or RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms.

Exclusion criteria:
History of allergy to the ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Pregnancy; Lactation. Impossibility of oral nutrition;

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**

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)
Double blinded

Blinding description
this is a double-blinded clinical trial, in which, a completely similar placebo to the drug is given to the main researcher by the manufacturer, and the drug and the placebo are distinguished only by the code that only the original researcher knows about. The doctor and the patient will be unaware of the drug/placebo product. The results will be recorded in the checklist based on the code registered on the drug and the analysis will be done based on the codes. At the end of the study, the meaning of each code will be determined.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqiyatallah Medical Sciences University

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

City
Tehran

Province
Tehran

Postal code
۱۴۳۵۹۱۵۴۷۱

Approval date
2020-05-02, 1399/02/13

Ethics committee reference number
IR.BMSU.REC.1399.124

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 at the hospitalization, but the result of baseline (before the initiation of intervention), and day 7 and day 21 from the initiation, is recorded.

Method of measurement
Physical examination,questionnaire

2

Description
Clinical symptoms (respiratory distress)

Timepoint
Daily monitoring at the hospitalization, but the result of

baseline (before the initiation of intervention), and day 7 and day 21 from the initiation, is recorded.

Method of measurement

Pulse-oxymetery device

3

Description

Clinical symptoms (fever)

Timepoint

Daily monitoring at the hospitalization, but the result of baseline (before the initiation of intervention), and day 7 and day 21 from the initiation, is recorded.

Method of measurement

Thermometer

Secondary outcomes

1

Description

Ferritin level

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Blood sample, laboratory analysis

2

Description

Serum level of Interleukin 6

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Elisa kit

3

Description

Serum level of tumor necrosis factor(TNF) alfa

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Elisa kit

4

Description

Serum level of Monocyte chemoattractant protein-1(MCP-1)

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Elisa kit

5

Description

Quality of life

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

The 36-Item Short Form Survey (SF-36) questionnaire

6

Description

Mood

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Profile of Mood States(POMS) questionnaire

7

Description

Anxiety

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Perceived Stress Scale (PSS) questionnaire

8

Description

C-reactive protein (CRP) level

Timepoint

Before the intervention initiation (baseline) and day 90's results will recorded on designed checklist.

Method of measurement

Blood sample, laboratory analysis

Intervention groups

1

Description

Intervention group: Provita Capsule (each capsule contain vitamin A, E, D, C, B family, Zn, Se, Para-biotic, and inactive ingredients, produced by Tak-Gen-Zist pharmaceutical company, Iran) 1 capsule, every 12 hours, for 21 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: Placebo Capsule(contain inactive ingredients similar to Provita's inactive ingredients, produced by Tak-Gen-Zist pharmaceutical company, Iran), 1 capsule, every 12 hours, for 21 days (In addition to 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
Mostafa Ghanei

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

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Email
mghaneister@gmail.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, Iran.

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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
80

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

2

Sponsor

Name of organization / entity
Takgen company

Full name of responsible person
Maryam Tajabadi

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4th Floor, No. 214, East Nosrat St.,Towhid Sq. Tehran

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Email
info@takgene.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Baqiyatallah University of Medical Science

Proportion provided by this source
20

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

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Seyed Hasan Saadat

Position
Assistant of Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

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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