

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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

۱۴۳۵۹۱۵۳۷۱

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-oxymetry 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.

City

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Province

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Postal code

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Phone

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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,
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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

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

Street address

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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Person responsible for updating data

Contact

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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