

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2020

Efficacy evaluation of inhalation therapy (nasal spray) of Interferon Beta-1a in hospitalized Covid-19 patients

Protocol summary

Study aim

Evaluation of 50% reduction of viral load or negative results of virus before Day 7

Design

A phase III, Placebo-controlled, Paralleled, double-blind, randomized clinical trial

Settings and conduct

This is a randomized double blind study at Baqiyatallah Hospital and other centers of the study at hospitalized covid-19 patients. Nasal spray of interferon beta 1a will be prepared by sponsor of the study (CinnaGen), the package of the test and placebo drug will have totally equal shape and size. The drugs will be coded by randomization code which was prepared by an independent statistical person. The dosage of the drug or placebo: One puff at each nostril, every 6 hours, for 7 days

Participants/Inclusion and exclusion criteria

Patients who have Covid-19 based on the CT-scan data or PCR and have no allergic sensitivity to the interferon products or participated in any other trials of Covid-19

Intervention groups

Test group: Concomitant with the national corona treatment recommendation (based on the Ministry of Health protocol: hydroxychloroquine, etc ..), patients will receive 1 puff of a nasal spray (CinnaGen Company) at each nostril, every 6 hours for 7 days. Control (Placebo) Group: Concomitant with the national corona treatment recommendation (based on the Ministry of Health protocol: hydroxychloroquine, etc .), patients will receive 1 puff of a nasal spray (CinnaGen Company) at each nostril, every 6 hours for 7 days.

Main outcome variables

The primary outcome was the evaluation of 50% reduction of viral load or negative results of virus before Day 7

General information

Reason for update

Due to the primary endpoint change, the protocol is updated

Acronym

IRCT registration information

IRCT registration number: **IRCT20200511047396N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **prospective**

Last update: **2020-06-28, 1399/04/08**

Update count: **1**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Ramin Ajdarzade

Name of organization / entity

CinnaGen

Country

Iran (Islamic Republic of)

Phone

+98 26 3667 0734

Email address

azhdarzadehm@cinnagen.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of inhalation therapy (nasal spray) of Interferon Beta-1a in hospitalized Covid-19 patients

Public title

Efficacy evaluation of inhalation therapy (nasal spray) of Interferon Beta-1a in hospitalized Covid-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have Covid-19 based on the CT-scan or RT-PCR findings Hospitalized patients Willingness to participate in the study for trial period and signing the informed consent form Age between 20-65

Exclusion criteria:

Pregnancy Breastfeeding Use of ARB/ACEi History of hypotension have no consent to participate in the study Allergic sensitivity to the interferon products Not availability of phone number or it is possible to be transferred to other hospitals Having the CKD or patients who need dialysis at the beginning of the study Having any disease or condition that based on the physician judgment cannot participate in the study Participation in any other trials of Covid-19

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (block sizes of 4) will be used to allocate drug or placebo to the patients of the study. Test drug or placebo will have randomization code which is specific for each patient and was generated by the randomization process. Randomization will not be exposed to the trial executers and will be provided to the investigator in non-transparent sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Test drug and placebo are totally similar and have same color, shape, and size and is not distinguishable by patients or investigators

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.BMSU.REC.1399.122

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The primary outcome was the evaluation of 50% reduction of viral load or negative results of virus before day 7

Timepoint

before drug administration, day 3, day 5, and day 7 (before negative result until day 7)

Method of measurement

RT-PCR test

Secondary outcomes

1

Description

Number of days with fever (more than 37.2) up to 7 days

Timepoint

Daily up to day 7

Method of measurement

Thermometer

2

Description

Number of days with dyspnea until day 7

Timepoint

Daily up to day 7

Method of measurement

Clinical examination by investigator or history review of the patients

3

Description

Number of days that patients need supplemental oxygenation up to day 7

Timepoint

Daily up to day 7

Method of measurement

Examination by investigator

4

Description

Change of laboratory results of patients before treatment and last day of study (day 7)

Timepoint

Before drug administration and last day of study

Method of measurement

Laboratory results

5

Description

Adverse events

Timepoint

Daily up to day 7

Method of measurement

Investigator report

6

Description

Number of days that patients have dry cough

Timepoint

Daily until day 7

Method of measurement

Examination by investigator

Intervention groups

1

Description

Intervention group: Concomitant with the national corona treatment recommendation (based on the Ministry of Health protocol: hydroxychloroquine etc...), patients will receive 1 puff (equall to 1000 IU of interferon beta 1a)of a nasal spray (CinnaGen Company) at each nostril, every 6 hours for 7 days

Category

Treatment - Drugs

2

Description

Control group: Concomitant with the national corona treatment recommendation (based on the Ministry of Health protocol: hydroxychloroquine etc...), patients will receive 1 puff of a nasal spray (CinnaGen Company) at each nostril, every 6 hours for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallal Hospital

Full name of responsible person

Ashraf Karbasi

Street address

Baqiyatallal Hospital

City

Tehran

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Tehran

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1435915371

Phone

+98 21 8126 2037

Email

ashraf.karbasi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CinnaGen company

Full name of responsible person

Dr. Haleh Hamedifar

Street address

No.2 , 7thSt., Simaye Iran St., Shahrak Gharb, Tehran, IRAN

City

Tehran

Province

Tehran

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1467635165

Phone

+98 26 3667 0334

Email

cinnagen@cinnagen.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

CinnaGen company

Proportion provided by this source

100

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

Ashraf Karbasi

Position

Principal investigator

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Latest degree

Subspecialist

Other areas of specialty/work

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Other areas of specialty/work

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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

Not applicable

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