

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### 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

**Recruitment complete**

##### 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

##### **Province**

Tehran

##### **Postal code**

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

##### **Postal code**

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

**Street address**

Baqiyatallah University of Medical Sciences

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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**

Ashraf Karbasi

**Position**

Principal Investigator

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for updating data****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

**Street address**

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ashraf.karbasi@yahoo.com

**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