Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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 Baqiyatallal 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 begining 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
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1435915371
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+98 21 8126 2037
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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
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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
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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
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