# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 2026

## Investigating the efficacy and safety of Interferon Beta1a nasal spray in controlling the symptoms of patients with COVID-19

### Protocol summary

**Study aim**
Investigating the efficacy and safety of Interferon Beta1a nasal spray in controlling the symptoms of patients with COVID-19

**Design**
This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

**Settings and conduct**
Patients who is admitted to Baqiyatallah hospital, and is meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

**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 ingredients; hypersensitivity reaction while taking this spray; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Chronic kidney disease, stage 3 to 5; Receiving ACEI/ARB group;

**Intervention groups**
Intervention group: Interferon Beta 1a nasal spray 1 puff in each nostril every 6 hours, for 14 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus). Control group: 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: **IRCT20080901001165N53**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**
Update count: **0**

**Registration date**
2020-05-14, 1399/02/25

**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**
2020-08-14, 1399/05/24

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the efficacy and safety of Interferon Beta1a nasal spray in controlling the symptoms of patients with COVID-19

**Public title**
Investigating the efficacy and safety of Interferon Beta1a nasal spray 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 this nasal spray ingredients; Hypersensitivity reaction while taking this nasal spray; 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. Chronic kidney disease, stage 3 to 5; Receiving ACEI/ARB group;

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Block Randomization method is used to randomized the patients. In this method, the number of people assigned to each group is usually almost equal. Blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as witnesses. The main goal in this method is to balance the number of participants in each group.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Baqiyatallah University of Medical Science

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

**City**
Tehran

**Province**
Tehran

**Postal code**
1435916471

**Approval date**
2013-05-03, 1392/02/13

**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

## Primary outcomes

### 1

**Description**
Clinical symptoms (dry cough)

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

**Method of measurement**
Physical examination,questionnaire

### 2

**Description**
Clinical symptoms (respiratory distress)

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

**Method of measurement**
Pulse-oxymetery device

### 3

**Description**
Clinical symptoms (fever)

**Timepoint**
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
**Method of measurement**
Thermometer

## Secondary outcomes

### 1

**Description**
Lab. tests changes
**Timepoint**
Daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.
**Method of measurement**
Blood sample, laboratory analysis

### 2

**Description**
Side effects
**Timepoint**
Daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.
**Method of measurement**
Physical examination

### 3

**Description**
Mortality
**Timepoint**
Day 14 from the initiation
**Method of measurement**
Clinical assessment

## Intervention groups

### 1

**Description**
Intervention group: Interferon Beta 1a nasal spray 1 puff in each nostril every 6 hours, for 14 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: 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**
Tehran
**Province**
Tehran
**Postal code**
1435916471
**Phone**
+98 21 8245 5393
**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.
**City**
Tehran
**Province**
Tehran
**Postal code**
1435916471
**Phone**
+98 21 8245 5393
**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**
Cinnagen company
**Full name of responsible person**
Khashayar Roshanzamir
**Street address**
No. 2, 7th St., Simai Iran St., Gharb Town, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1467635165
**Phone**
+98 21 8856 1575
**Email**
info@cinnagen.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
**Street address**
Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran.
**City**
Tehran
**Province**
Tehran
**Postal code**
1435916471
**Phone**
+98 21 8245 5393
**Email**
saadat350@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Yunes Panahi
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Critical Care Pharmacotherapy
**Street address**
Baqiyatallah university of medical science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1435916471
**Phone**
+98 21 8245 5393
**Email**
Yunespanahi@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Parisa Kianpour
**Position**
Specialist
**Latest degree**
Specialist
**Other areas of specialty/work**
Pharmacotherapy
**Street address**
Pharmacy faculty, Tehran University of medical science, 16-Azar St., Enghelab Sq., Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1417614411
**Phone**
+98 21 6695 4709
**Email**
parisa_kianpour@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**
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