Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Efficacy and safety of Interferon beta-1-a in the management of the outpatients with mild to moderate COVID-19: A preliminary study

Protocol summary

Study aim

Efficacy and safety of Interferon β-1a in the management of the outpatients with mild to moderate COVID-19

Design

A randomized clinical trial, case-control, parallel with a cross-sectional design for 6 months. The randomization was performed by permuted block randomization and block sizes of 4.

Settings and conduct

Eligible patients who are referred to the Saghi Clinic in Tehran, Iran, are randomly divided into intervention and control groups. Patients in the intervention group receive interferon β-1a (ReciGen®) plus conservative therapy whereas patients in the control group received only conservative therapy.

Participants/Inclusion and exclusion criteria

Including criteria are confirmed COVID-19, based on reverse transcriptase-polymerase chain reaction, mild to moderate COVID-19, and within 48 hours of the onset of the symptoms; Age younger than 18 years old, diagnosis of COVID-19 based on clinical criteria without positive rt-PCR results, the onset of symptoms more than 48 hours, patients with severe to critical COVID-19, immunocompromised state, receiving any antiviral or anti-inflammatory drug, liver enzymes 3 times higher than the normal range, psychotic disorders, platelet count below 50,000, hemoglobin less than 10 grams per deciliter, lactation and pregnancy were considered as exclusion criteria.

Intervention groups

Patients in the intervention group receive interferon β-1a 12 million units subcutaneously every other day for three doses plus conservative therapy including acetaminophen and antihistamine. Patients in the control group received only conservative therapy.

Main outcome variables

body temperature; systolic blood pressure; diastolic blood pressure; respiratory rate; pulse rate; and level of oxygen saturation in the peripheral circulation.

General information

Reason for update

Acronym

COVID-19

IRCT registration information

IRCT registration number: **IRCT20120703010178N25**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **prospective**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-21, 1400/05/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy and safety of Interferon beta-1-a in the management of the outpatients with mild to moderate COVID-19: A preliminary study

Public title
Efficacy and safety of Interferon beta-1-a in mild to moderate COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmed COVID-19, based on reverse transcriptase-polymerase chain reaction (rt-PCR) Patients with mild to moderate COVID-19 Within 48 hours of the onset of the symptoms

Exclusion criteria:
Age younger than 18 years old Diagnosis of COVID-19 based on clinical criteria without positive rt-PCR results The onset of symptoms more than 48 hours Patients with severe to critical COVID-19 Immunocompromised state Receiving any antiviral or anti-inflammatory drug Lactation and pregnancy Liver enzymes 3 times higher than the normal range Psychotic disorders Platelet count below 50,000 Hemoglobin less than 10 grams per deciliter

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
The randomization was performed by permuted block randomization and block sizes of 4.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients in the intervention group received interferon β-1a plus conservative therapy whereas patients in the control group received only conservative therapy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
13th Floor, Block A, Headquarters of the Ministry of Health and Medical Education, Iran TV St., Between South Flamek and Zarafshan, Qods (West) Town

City
Tehran

Province
Tehran

Postal code
1991953381

Approval date
2021-06-29, 1400/04/08

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.080

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Body temperature

Timepoint
In the beginning of the study and after 7 days of the treatment

Method of measurement
Thermometer

2

Description
Systolic blood pressure

Timepoint
In the beginning of the study and after 7 days of the treatment

Method of measurement
sphygmomanometer

3

Description
Diastolic blood pressure

Timepoint
In the beginning of the study and after 7 days of the treatment

Method of measurement
sphygmomanometer

4

Description
Respiratory rate
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
chronometer

5

Description
Pulse rate
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
chronometer

6

Description
level of oxygen saturation in the peripheral circulation
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
pulse oximeter

Secondary outcomes

1

Description
nausea
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
Self reporting

2

Description
Abdominal pain
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
Self reporting

3

Description
Injection site pain
Timepoint
After 7 days of the treatment
Method of measurement
Self reporting

4

Description
Myalgia
Timepoint
In the beginning of the study and after 7 days of the treatment
Method of measurement
Self reporting

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive interferon β-1a (ReciGen®) 12 million units subcutaneously every other day for three doses plus conservative therapy including acetaminophen and antihistamine.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group receive only conservative therapy including acetaminophen and antihistamine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Saghi clinic
Full name of responsible person
Seyed Mohammad seyed Hosseini
Street address
Ayatollah Kashani Street, next to Hakim Bridge
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Tehran
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1415684543
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mehrdad_pana@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Afshin Zarghi

Street address
Velenjak Street, Shahid Chamran High Way

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1991953381

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urm@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Sistanizad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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3rd floor, Faculty of Pharmacy, Shahid Beheshti Medical University, Vali-e-asr Ave, Niyayesh Junction

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person
Elham Pourheidar

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Specialist

Other areas of specialty/work
Medical Pharmacy

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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