

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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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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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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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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Elham Pourheidar

Position

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Latest degree

Specialist

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

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