

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluating the therapeutic and adverse effects of Interferon beta 1-a subcutaneous administration in patients with novel Coronavirus (COVID-19)

Protocol summary

Study aim

Evaluating the therapeutic and adverse effects of Interferon beta 1-a subcutaneous administration in patients with new Coronavirus (COVID-19)

Design

Non-controlled clinical trial

Settings and conduct

Dr. Masih Daneshvari Hospital

Participants/Inclusion and exclusion criteria

Patients with confirmed COVID-19 who are in severe phase and did not have chronic kidney or liver diseases and are not pregnant or breastfeeder.

Intervention groups

Patients receive Hydroxychloroquine 400 mg P.O. BID and Oseltamivir 75 mg P.O. BID and Lopinavir-Ritonavir 200/50 mg P.O. two tablets BID for five days. Also, patients receive Interferon beta-1a 44 mg every other day S.C until 10 days.

Main outcome variables

Clinical symptoms; laboratory parameters; imaging studies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N12**

Registration date: **2020-03-23, 1399/01/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-23, 1399/01/04**

Update count: **0**

Registration date

2020-03-23, 1399/01/04

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-03, 1398/12/13

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the therapeutic and adverse effects of Interferon beta 1-a subcutaneous administration in patients with novel Coronavirus (COVID-19)

Public title

Evaluating the therapeutic and adverse effects of Interferon beta 1-a in patients with novel Coronavirus(COVID-19)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laboratory confirmed COVID-19 with RT-PCR Respiratory

rate > 30/min Oxygen saturation < 90% PaO₂/FiO₂ < 300mmHg

Exclusion criteria:

Chronic kidney Disease Pregnancy or breastfeeding Drug allergy history Pneumonia due to influenza virus, bacterial pneumonia, fungal pneumonia, and noninfectious causes Chronic liver disease Acute kidney injury

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Institute of Tuberculosis and Lung Diseases

Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

City

Tehran

Province

Tehran

Postal code

19569-44413

Approval date

2020-02-25, 1398/12/06

Ethics committee reference number

IR.SBMU.NRITLD.REC.1398.102

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Clinical response to therapy

Timepoint

Daily

Method of measurement

Clinical symptoms

Secondary outcomes

1

Description

Hospitalization duration

Timepoint

At admission time and discharge time

Method of measurement

Clinical records

2

Description

Lung radiology changes

Timepoint

At admission time and seven and 14 days later

Method of measurement

Computed tomography

3

Description

Adverse Drug Reaction

Timepoint

Daily

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Tab Hydroxychloroquine 400 mg P.O. BID for five days plus Tab Oseltamivir 75 mg P.O. BID for five days plus Tab Lopinavir-Ritonavir 200/50 mg P.O. two tablets BID for five days plus Interferon beta-1a 44 mg every other day S.C for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

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info@nritld.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Payam Tabarsi

Street address

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tabarsi@nritld.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

Farzaneh Dastan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Payam Tabarsi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Saffaei

Position

Clinical Pharmacy Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

What processes are involved for a request to access data/document

Official letter to the researchers

Comments