Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

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

Public title
Evaluting 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 plusTab 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
Street address
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2712 3000
Fax
+98 21 2610 9490
Email
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
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2712 3000
Email
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
Street address
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2610 9490
Fax
+98 21 8887 3704
Email
f_dastan@sbmu.ac.ir

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
Street address
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2712 3000
Email
tabarsi@nritld.ac.ir

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
Street address
Niayesh Highway., Valiasr Ave.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
alisaffaei.ss@gmail.com

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 mounts 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