Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel Coronavirus (COVID-19)

Protocol summary

Study aim
Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel 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 and high level of interleukin-6
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. Also, patients receive Tocilizumab at dose of 400 mg I.V infusion.
Main outcome variables
Clinical response to therapy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20151227025726N13**
Registration date: **2020-03-26, 1399/01/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-26, 1399/01/07**
Update count: **0**
Registration date
2020-03-26, 1399/01/07

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
2020-03-11, 1398/12/21
Expected recruitment end date
2020-05-10, 1399/02/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel Coronavirus (COVID-19)

Public title
Evaluation the Efficacy and Safety of Tocilizumab in 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 High level of serum Interleukin-6 Age over 18 years old
Exclusion criteria:
Chronic kidney Disease Acute kidney injury Pregnancy or

breastfeeding Drug allergy history Pneumonia due to influenza virus, bacterial pneumonia, fungal pneumonia, and noninfectious causes Chronic liver disease History of latent or active tuberculosis Patients with human immunodeficiency virus

Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
2020-03-10, 1398/12/20
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.002

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
RA01.0
ICD-10 code description
Confirmed diagnosis of COVID-19

Primary outcomes

1

Description
Fever
Timepoint
Daily
Method of measurement
Thermometer

2

Description
Cough
Timepoint
Daily
Method of measurement
Observation

3

Description
Dyspnea
Timepoint
Daily
Method of measurement
Observation

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

4

Description
Virological clearance
Timepoint
At admission time and seven and 14 days later
Method of measurement
Reverse transcription polymerase chain reaction

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 Tocilizumab (Actemra) 400 mg I.V infusion as a single dose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
Street address
Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
f_dastan@sbmu.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
Afshin Zarghi
Street address
3 th floor, School of Medicine, Evin St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 23871
Email
mpd@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
Farzaneh Dastan
Position
Assisstant Professor, Clinical Pharmacy Specialist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Valieasr St., Intersection of Niyayesh Highway, Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Fax
Email
f_dastan@sbmu.ac.ir
Web page address

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