

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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@sbm.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 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 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

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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

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Province

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1983963113

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+98 21 23871

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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

Assistant 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

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1991953381

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Fax

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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

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Email

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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

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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Phone