Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the Effects of Tocilizumab Administration in the Cytokine Release Phase on the CT Scan Findings and Clinical Outcomes in Hospitalized COVID-19 Patients

Protocol summary

Study aim

Determination of the effect of tocilizumab on pulmonary CT scan and cytokine release syndrome in COVID-19 hospitalized patients

Design

An Interventional study without control group and not blinded on 50 patients.

Settings and conduct

This study is conducted in two public university centers and a private center in Tehran. Patients who meet the inclusion criteria are treated with tosilizumab. In coordination with the treating physician before the drug is injected, CT scan of the primary multiplexer and baseline is performed for the patients. Then, CT scan is requested in all patients on days 7, 14 and 21 to evaluate the response to treatment.

Participants/Inclusion and exclusion criteria

Patients between the ages of 18 and 70 who have been diagnosed with COVID 19 by RT-PCR are in the severe or critical stage of the disease and also have six levels of interleukin above 15 pg/ml or CRP above 100 are included. Pregnant and lactating patients with renal failure, hepatic impairment, hypersensitivity reaction during tocilizumab injection, Mild stage of disease, platelet less than 100,000 or ANC less than 500, active infections, history of active gastric ulcers, and patients with positive viral markers are excluded.

Intervention groups

Patients who meet the inclusion criteria are treated with tosilizumab. To inject the drug, 400 mg of (Tocilizumab) ACTEMRA is diluted in at least 100 ml of normal saline ٪ 0.9 and it is slowly injected intravenously within at least one hour. During the injection, the patient's vital signs and the injection site are monitored for any complications.

Main outcome variables

CT Scan result; Need for hospitalization and duration of hospitalization in the ICU; The need for a mechanical ventilator and the length of the hospitalization model; Occurrence of any side effects; Therapeutic outcome of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N29**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

Registration date

2022-02-16, 1400/11/27

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 270 5933

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effects of Tocilizumab Administration in the Cytokine Release Phase on the CT Scan Findings and Clinical Outcomes in Hospitalized COVID-19 Patients

Public title
Evaluation of the Effects of Tocilizumab Administration in Hospitalized COVID-19 Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18 and 70 years old Laboratory confirmed COVID-19 with RT-PCR Be in severe or critical stage of the disease Have interleukin-6 levels above 15 picogram per milliliter or CRP above 100 miligram per liter
Exclusion criteria:
Acute or chronic renal failure (Increase in creatinine by more than 3.0 in the last 48 hours or GFR less than 30 mL/min) Liver failure (more than 5-fold increase in liver enzymes in asymptomatic patients or more than 3-fold increase in liver enzymes in symptomatic patients or Child Pugh C, D) Hypersensitivity reaction during tocilizumbe injection with severe extrusion and symptoms of anaphylactic shock Mild stage of the disease Pregnant and lactating patients Patients with platelets less than 100,000 or ANC less than 5 Patients with Latent TB or Active TB or any active infection History of active gastric ulcer Patients with positive viral marker
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Ethics Committee of Medical School-Iran University of Medical Sciences
Street address
School of Medicine, Iran University of Medical Sciences, Hemmat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-05-17, 1400/02/27
Ethics committee reference number
IR.IUMS.FMD.REC.1400.132

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Mortality
Timepoint
Days 7, 14 and 21 of hospitalization
Method of measurement
Medical record

2

Description
Need for intubation
Timepoint
Daily until discharge
Method of measurement
Medical record

3

Description
Lung radiological changes
Timepoint

Before receiving tocilizumab and after discharge

Method of measurement

Computed tomography

Secondary outcomes

1

Description

Number of days admitted to critical care unit

Timepoint

Daily until discharge

Method of measurement

Medical record

2

Description

Length of hospital stay

Timepoint

Daily until discharge

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: Dilute 400 mg of ACTEMRA (Tocilizumab) in at least 100 ml of normal saline 0.9 and give it slowly intravenously over at least one hour. The drug should be given at 2 to 8 ° C before injection. Store in the refrigerator.

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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Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Sahar Yousefian

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity
Iran University of Medical Sciences
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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 the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
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 through Email (fzh.dastan@gmail.com)
Comments