Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of Efficacy and Safety of Inhaled Tocilizumab in Comparison with Intravenous Tocilizumab in Hospitalized Patients with COVID-19

Protocol summary

Study aim

Determination of efficacy and safety of inhaled tocilizumab versus intravenous tocilizumab

Design

A controlled, parallel group, randomised, phase 3 clinical trial on 100 patients. Permuted block randomisation will be used by using Sealedenvelope site. At first, both groups receive 400 mg tocilizumab by intravenous infusion during one hour. After 12 hours, in the case group, 400 mg tocilizumab will be administered by nebulization method (5 cc every 6 hours) and in the control group 400 mg tocilizumab will be administered by intravenous infusion during one hour.

Settings and conduct

Dr. Masih Daneshvari Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients with confirmed COVID-19 diagnosis (RT-PCR positive) and severe lung involvement (oxygen saturation < 90% or lung involvement >50% or respiratory rate >30) Exclusion criteria: sensitivity to tocilizumab or one of the components of drug formulation, ANC<500 cells/mm3, Pelatelet<50,000 cells/mm3, hepatic transaminase > 5 times normal range or mild increase in liver transaminases along with signs and symptoms of liver disorder, history of malignancy, diverticulitis, positive procalcitonin and active infection , concurrent use of other rheumatoid therapy medications

Intervention groups

At first, both groups will be received 400 mg tocilizumab by intravenous infusion during one hour. After 12 hours, in the case group, 400 mg tocilizumab will be administered by nebulization method (5 cc every 6 hours) and in the control group 400 mg tocilizumab will be administered by intravenous infusion during one hour. Both groups will receive standard diet including ramdesivir, dexamethasone, enoxaparin and supportive therapies.

Main outcome variables

Mortality rate, length of hospital stay, need for ICU hospitalization, need for mechanical ventilation, oxygenation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N27**
Registration date: **2021-09-25, 1400/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-25, 1400/07/03**
Update count: **0**

Registration date

2021-09-25, 1400/07/03

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

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Efficacy and Safety of Inhaled Tocilizumab in Comparison with Intravenous Tocilizumab in Hospitalized Patients with COVID-19

Public title
Comparison of Inhaled Tocilizumab with Intravenous Tocilizumab in hospitalized patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18 and 100 years old. Laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) or CT scan. Have signed the consent form. O2 saturation < 90% (at room air) or lung involvement >50% or respiratory rate >30 CRP > 75 mg/l IL-6 > 15 pg/ml
Exclusion criteria:
Allergy to Tocilizumab or one of the components of drug formulations. ANC < 500 cells/mm Pelatelet < 50000 cells/mm Hepatic transaminases > 5 times normal range or mild increase in liver transaminases associated with signs and symptoms of liver disorder History of malignancy Diverticulitis Positive procalcitonin and active infection (including latent or active tuberculosis infection) Taking other rheumatoid drugs at the same time
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method was used in this study. Twenty five blocks including 4 patients generated with online website (www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, 2 patients will be assigned to inhaled tocilizumab group and 2 patients will be assigned to intravenous tocilizumab group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe of Shahid Beheshti University of Medical Sciences
Street address
3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2021-06-10, 1400/03/20
Ethics committee reference number
IR.SBMU.NRITLD.REC.1400.016

Health conditions studied

1

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

Primary outcomes

1

Description
28 days mortality
Timepoint
From the first day of admission until 28 days
Method of measurement
Medical record

2

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

3

Description
Oxyganation rate
Timepoint

Daily until discharge

Method of measurement

Medical record

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

3

Description

Lung radiological changes

Timepoint

First day of the study then at discharge

Method of measurement

Computed tomography

4

Description

Inflammation biomarkers (CRP، IL-6، LDH، Ferritin)

Timepoint

Before first dose and 72 hours after second dose

Method of measurement

Medical record

Intervention groups

1

Description

Case group: At first receive 400 mg tocilizumab by intravenous infusion during one hour. After 12 hours, 400 mg tocilizumab (Temziva, Cinnagen) will be administered by nebulization method (5 cc every 6 hours) .

Category

Treatment - Drugs

2

Description

Control group: At first receive 400 mg tocilizumab by intravenous infusion during one hour. After 12 hours, 400 mg tocilizumab (Temziva, Cinnagen) will be administered by intravenous infusion during one hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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

Hamidreza Jamaati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Farzaneh Dastan

Position

Assisstant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sahar Yousefian

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

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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