Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the Effectiveness of Two Different Regimens Based on Tosilizumab and Baricitinib in Patients with COVID-19 Respiratory Distress Syndrome

Protocol summary

Study aim

Determining the effectiveness of tosilizumab and comparing it with administration of tosilizumab and baricitinib in patients with COVID-19 respiratory distress syndrome

Design

A controlled, parallel groups, randomized, single blinded and phase 3 clinical trial on 60 patients. The online site (www.sealedenvelope.com/simple-randomiser/v1/lists) and the randomization block method are used for randomization.

Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: Sixty patients with COVID-19 are randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria

Patients between the ages of 18 and 100 years who have been diagnosed with COVID-19 by RT-PCR and be in the severe stage of the disease and have also signed the study consent form are included. Pregnant and lactating patients with renal insufficiency, liver failure, hypersensitivity reaction, Mild stage of the disease, intubated patients and patients who are expected to die in less than 48 hours are excluded from the study.

Intervention groups

Patients in the control group received a single dose of 400 mg tocilizumab as a slow intravenous injection, and in the case group, patients received baricitinab at a dose of 4 mg daily for 14 days or until discharge in addition to a 400 mg dose of slow intravenous tocilizumab. In both groups, a second dose of tocilizumbe is given if necessary.

Main outcome variables

Duration of hospitalization; Duration of hospitalization in the ICU; Mortality rate; Clinical and paraclinical indicators; CT scan of the lungs at the beginning and end of the study; Occurrence of any side effects; Outcomes of patients (recovery, death)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N30**
Registration date: **2022-02-28, 1400/12/09**
Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**
Update count: **0**

Registration date

2022-02-28, 1400/12/09

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

2022-03-11, 1400/12/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Two Different Regimens Based on Tosilizumab and Baricitinib in Patients with COVID-19 Respiratory Distress Syndrome

Public title

Evaluation of the Effectiveness of Two Different Regimens Based on Tosilizumab and Baricitinib in Patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 100 years old Laboratory confirmed COVID-19 with RT-PCR Be in severe stage of the disease Have signed the consent to participate in the study

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 to tocilizumab or baricitinib with severe extravasation and symptoms of anaphylactic shock Mild stage of the disease Pregnant and lactating patients Patients who have been intubated Patients who are expected to die in the next 48 hours

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. Fifteen blocks including 4 patients generated with online website (www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, 2 patients will be assigned to baricitinib group and 2 patients will be assigned to tocilizumab group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Investigator is blind to the study groups until the end of the study.

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

2022-01-25, 1400/11/05

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.296

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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 intubation

Timepoint

Daily until discharge

Method of measurement

Medical record

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
Daily until discharge
Method of measurement
Medical record

2

Description
Number of days admitted to critical care unit
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
Need for a second dose of tosilizumab
Timepoint
Daily until discharge
Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: In addition to receiving tosilizumab at a dose of 400 mg by slow intravenous injection, patients receive baricitinib as a dose of 4 mg daily for 14 days or until discharge.
Category
Treatment - Drugs

2

Description
Control group: Patients receive a single dose of 400 mg tosilizumab as a slow intravenous injection.
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.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
f_dastan@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
3rd 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
Sahar Yousefian
Position
Hospital pharmacist
Latest degree
Medical doctor
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 2712 2227
Email
saahar26@yahoo.com

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
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Intersection of Niyayesh Highway, Valieasr St.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 2712 2227
Email
f_dastan@sbmu.ac.ir

Person responsible for updating data

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
Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 5050
Email
payamtabarsi@yahoo.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 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