

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparisson of the effectiveness of Tocilizumab and Tofacitinib on the outcomes of patients with severe COVID-19

Protocol summary

Study aim

Comparisson of the effectiveness of Tocilizumab and Tofacitinib on the outcomes of patients with severe COVID-19

Design

Randomized open label clinical trial, with two arms with 1: 1 allocation ratio

Settings and conduct

This study will perform on severe COVID-19 patients admitted to Labbafinejad Hospital in 2022. Patients are divided into groups A and B and receive medication according to the protocol. The medical team will evaluate daily symptoms, laboratory tests, and overall outcomes for up to 14 days or discharge / death time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Laboratory confirmation of COVID-19 virus by PCR, severe cases according to the World Health Organization guideline, body mass index less than 40 kg / m², no immunosuppressive diseases, non-pregnant and non-lactating women, Serum CRP level greater than 75 mg / L, do not receive immunomodulatory drugs for 6 months before, no history of severe hypersensitivity to tosilizumab and tofacitinib, no history of active gastric ulcer, active diverticulitis and other gastrointestinal diseases with risk of intestinal perforation, no active hepatitis or tuberculosis or an infection other than COVID-19. Exclusion criteria: severe drug allergy and anaphylactic shock, death in the first 24 hours of hospitalization, increase in liver enzymes to more than 10 times the normal upper limit, decrease in neutrophil count to less than 500 cells per microliter, decrease in platelet count to less than 50,000 cells per microliter, GFR less than 30 ml per minute.

Intervention groups

Group A will receive a dose of tosilizumab intravenous infusion (8 mg / kg up to a maximum of 800 mg). Group B will be treated with oral tofacitinib (10 mg every 12 hours for 14 days).

Main outcome variables

Death, hospitalization in intensive care unit, use of mechanical ventilation, hospitalization length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052358N3**

Registration date: **2022-04-01, 1401/01/12**

Registration timing: **prospective**

Last update: **2022-04-01, 1401/01/12**

Update count: **0**

Registration date

2022-04-01, 1401/01/12

Registrant information

Name

Amirreza Keyvanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4483 1899

Email address

amirrezakeyvanfar@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisson of the effectiveness of Tocilizumab and Tofacitinib on the outcomes of patients with severe COVID-19

Public title

Comparisson of the effectiveness of Tocilizumab and Tofacitinib on the outcomes of patients with severe COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Laboratory confirmation of COVID-19 virus by PCR
Severe cases according to the World Health Organization guideline (peripheral blood oxygen saturation less than 90%, respiratory rate more than 30 per minute or symptoms of severe respiratory distress such as use of auxillary respiratory muscles or inability to complete sentences) Body mass index less than 40 kg per square meter No immunosuppressive diseases (primary, secondary and organ transplant defects, chemotherapy or radiotherapy) Patient willingness to participate in the study Non-pregnant and non-lactating women Serum CRP level greater than 75 mg / L Do not receive immunomodulatory drugs for 6 months before No history of severe hypersensitivity to tosilizumab and tofacitinib and similar compounds No history of active gastric ulcer, active diverticulitis and other gastrointestinal diseases with risk of intestinal perforation No active hepatitis or tuberculosis or a bacterial or fungal or viral infection other than COVID-19 No history of chronic kidney disease (GFR less than 30 ml / min)

Exclusion criteria:

Severe drug allergy and anaphylactic shock Death in the first 24 hours of hospitalization Increase in liver enzymes to more than 10 times the normal upper limit Decrease in neutrophil count to less than 500 cells per microliter Decrease in platelet count to less than 50,000 cells per microliter GFR less than 30 ml per minute

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is a simple randomization that is done in the form of individual random units. The tool used to do this is a random numbers table. The method of constructing a random sequence is that first the researcher selects one of the numbers with his eyes closed and then moves in the right direction. Odd

numbers are considered for intervention and even numbers are for control. Random concealment is also performed using sequentially numbered sealed opaque envelopes (SNOSE).

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**

Organizational Committee of Ethics in Biomedical Research, Shahid Beheshti University of Medical Sci

Street address

Shahid Beheshti University of medical sciences, Arabi St., Daneshjoo Blvd., Yaman St., Chamran highway.

City

Tehran

Province

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Postal code

1985717443

Approval date

2022-03-12, 1400/12/21

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1238

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Mortality

Timepoint

Until the 14th day of hospitalization or discharge / death

Method of measurement

Patient medical record

2

Description

Admission to the intensive care unit

Timepoint

Until the 14th day of hospitalization or discharge / death

Method of measurement

Patient medical record

3

Description

Use of mechanical ventilation

Timepoint

Until the 14th day of hospitalization or discharge / death

Method of measurement

Patient medical record

4

Description

Hospitalization length

Timepoint

Until the 14th day of hospitalization or discharge / death

Method of measurement

Patient medical record

Secondary outcomes

1

Description

Body temperature

Timepoint

Daily and up to 14 days daily or discharge / death time

Method of measurement

Thermometer

2

Description

Respiratory rate

Timepoint

Daily and up to 14 days daily or discharge / death time

Method of measurement

Physical examination by physician

3

Description

Oxygen saturation

Timepoint

Daily and up to 14 days daily or discharge / death time

Method of measurement

Pulse oximeter

4

Description

Serum CRP level

Timepoint

Daily and up to 14 days daily or discharge / death time

Method of measurement

Laboratory report

5

Description

Serum LDH level

Timepoint

Daily and up to 14 days daily or discharge / death time

Method of measurement

Laboratory report

Intervention groups

1

Description

Intervention group A: Group A will receive a dose of tosilizumab intravenous infusion (8 mg / kg to a maximum of 800 mg) in addition to routine treatment according to national protocol.

Category

Treatment - Drugs

2

Description

Intervention group B: Group B, in addition to routine treatment according to the national protocol, will be treated with oral tofacitinib (10 mg every 12 hours for 14 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad hospital

Full name of responsible person

Amirreza Keyvanfar

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9th Boostan St., Pasdaran, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

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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

Amirreza Keyvanfar

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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