Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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)

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+98 21 4483 1899

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amirrezakeyvanfar@sbmu.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
Tehran

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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
Street address
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 assisstant
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

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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