Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Efficacy of Tocilizumab in Hospitalized Patients with COVID-19: An open-label placebo-controlled clinical study

Protocol summary

Study aim

This study will be performed to determine the efficacy of tocilizumab and standard treatment regimen versus placebo and standard treatment regimen according to national guidelines in the treatment of hospitalized patients with COVID-19.

Design

A two-arm, parallel, randomized, open-label, controlled clinical trial on 60 hospitalized COVID-19 patients. Random blocks will be used for randomization.

Settings and conduct

This study will be performed on hospitalized COVID-19 patients in Ayatollah Rouhani hospital under infectious disease, pulmonologist, and anesthesiologist supervision. After confirming the disease with the RT-PCR test and check the inclusion criteria, patients will be randomly assigned to one of the two groups. This study is designed as an open-label study.

Participants/Inclusion and exclusion criteria

Summary of inclusion criteria: Both genders;> 18 years of age; Confirmation of COVID-19 with RT-PCR; Need for hospitalization; No need for mechanical ventilation; No need to more than 10 L/min of supplemental oxygen by any device; Being in a severe COVID-19 phase; Having at least one of the following: CRP > 50 mg/L, LDH > 350 U/L, D-Dimer > 1000 ng/mL. Exclusion criteria: Active TB; Any history of intestinal diverticulitis or perforation; Pregnant and/or breastfeeding women; History of allergy to tocilizumab; Liver functions tests > 5 ULN; Concomitant use of any immunosuppressive drug 7) Any history of progressive neuromuscular diseases.

Intervention groups

The control group will receive placebo with a standard treatment regimen. The intervention group will receive a standard treatment regimen with two consecutive IV infusions of tocilizumab at a dose of 8 mg/kg every 12 hours.

Main outcome variables

Time since intervention to the need for mechanical ventilation and intubation or death for those who died before intubation (within 28 days).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049134N2**
Registration date: **2021-06-04, 1400/03/14**
Registration timing: **prospective**

Last update: **2021-06-04, 1400/03/14**
Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Tocilizumab in Hospitalized Patients with COVID-19: An open-label placebo-controlled clinical study

Public title
Efficacy of tocilizumab in the treatment of hospitalized patients with COVD-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women of at least 18 years of age capable of providing informed consent. Confirmation of COVID-19 with RT-PCR. Need for hospitalization. No need for mechanical ventilation. No need to more than 10 L/min of supplemental oxygen by any device. Being in a severe COVID-19 phase (at least 2 of the following): Fever > 38 ° C in the last 72 hours, Evidence of pulmonary involvement on chest x-ray (50% progression in the last 48 hours), Dependence on supplemental oxygen to maintain a blood oxygen saturation > 90% Having at least one of the following: CRP > 50 mg/L, LDH > 350 U/L, D-Dimer > 1000 ng/mL

Exclusion criteria:
Patients more than 70 years of age with a history of any of the following in the last six months: Class III / IV Heart Failure Based on the New York Heart Association (NYHA) classification, Insulin-dependent diabetes, Angina pectoris, Malignancy Uncontrolled bacterial, fungal, or viral infection (other than COVID-19). Active TB Any history of any progressive neuromuscular disease. Any previous history of treatment with immunosuppressive medications in the last 28 days. Concomitant use of any immunosuppressive drug that puts the patient at greater clinical risk. Any history of allergy to Tocilizumab. Any history of receiving convalescent plasma therapy Any history of intestinal diverticulitis or perforation Absolute neutrophil count (ANC) < 500 or platelets < 50,000 AST or ALT > 5 times the upper limits of normal Pregnant women or those intending to become pregnant in the next 90 days Breastfeeding women

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Unit randomization is done by block method with a block size of 4. For each of the 6 possible cases for the quadruple block, the numbers are assigned as follows AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6). With the help of a table of random numbers, the numbers between 1 and 6 are selected, and the treatment allocation list is determined according to each number. To execute the generated random sequence, the method of hiding coded boxes or cans is used. In this method, the cans are numbered in a random sequence. Inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written is provided to the executor with the condition that the boxes are completely sealed. The researcher assigns patients to the standard intervention and treatment group based on patients' admission orders. Tools: Create random sequences of 4 random blocks Concealment to execute random sequences on study participants will be done. How to make blocks: Randomly select the block and read the letters from right to left. Hiding will be done by the method of cans that are numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Babol University of Medical Sciences

Street address
GanjAfrooz Blvd.

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Postal code
4717647745

Approval date
2021-05-31, 1400/03/10

Ethics committee reference number
IR.MUBABOL.REC.1400.144

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
The time from the administration of the agent or placebo to the need for mechanical ventilation and intubation or death for whom died before intubation (within 28 days).
Timepoint
4, 7, 14, 21 and 28 days after Tocilizumab or placebo administration
Method of measurement
Examination of the patients by the research team

Secondary outcomes

1

Description
Time since prescribing the investigated agent or placebo to the deterioration of patient status for one degree (for patients with a score of ≥ 3 on the clinical improvement scale at the time of enrollment) or two degrees (for patients with a score = 2 on the clinical improvement scale at the time of enrollment)
Timepoint
4, 7, 14, 21, and 28 days after Tocilizumab or placebo administration
Method of measurement
Examination of the patients by the research team

2

Description
Time since the administration of the study agent or placebo to when the patients with a score of ≥ 3 on the clinical improvement scale at the time of enrollment do not require oxygen supplementation (within 28 days).
Timepoint
4, 7, 14, 21, and 28 days after Tocilizumab or placebo administration
Method of measurement
Examination of the patients by the research team

Intervention groups

1

Description
Control group: Patients in this group receive a placebo at a dose of 8 mg/kg (up to a maximum dose of 800 mg/kg) by two consecutive intravenous infusions 12 hours apart in addition to standard treatment based on national guidelines for the treatment and management of COVID-19.
Category
Placebo

2

Description
Intervention group: Patients in this group receive tocilizumab at a dose of 8 mg/kg (up to a maximum dose of 800 mg/kg) by two consecutive intravenous infusions 12 hours apart in addition to standard treatment based on national guidelines for the treatment and management of COVID-19.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Mostafa Javanian
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Sponsors / Funding sources

1

Sponsor
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Web page address
http://research.mubabol.ac.ir/about/?id=350
Grant name
Grant code / Reference number
724133634
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Babol 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
Babol University of Medical Sciences

Full name of responsible person
Mohammad Barary

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Latest degree
A Level or less

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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All participants' personal data can be shared after the anonymization of individuals.

When the data will become available and for how long
Six months after the end of the study and publication of the article

To whom data/document is available
The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no specific preconditions.

From where data/document is obtainable

They should send their request to the person in charge of the study, Dr. Mostafa Javanian, with the e-mail address: mjavanian@gmail.com.

What processes are involved for a request to access data/document

On average, it will take two weeks to process the application.

Comments