# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

**Name**

Mohammad Barary

**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.

**City**
Babol

**Province**
Mazandaran

**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**
**Name of organization / entity**
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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 scientific inquiries

**Contact**

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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
General Practitioner

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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**