

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of IL-6 inhibitor (Tocilizumab) on the prognosis of covid-19 patients with acute respiratory failure

#### Protocol summary

##### Study aim

1-Effect of IL-6 inhibitor in preventing the progression of pulmonary inflammation 2-IL-6 inhibition and cytokine release prevention can subside hypoxic respiratory failure of COVID-19 patients 3-IL-6 inhibition can reduce mortality of respiratory failure in COVID-19 patients 4-IL-6 inhibition may reduce end organ failure in COVID-19 patients

##### Design

10 Covid-19 patients with clinical and laboratory confirmation and acute respiratory failure admitted to the intensive care unit of Imam Reza Hospital after ruling out of latent TB by IGRA test, 400 mg Tocilizumab is prescribed as a slow intravenous infusion and the results will be compared with a similar group that did not receive the drug.

##### Settings and conduct

10 Covid-19 patients with acute respiratory failure in ICU of Imam Reza Hospital after IGRA testing to rule out TB Tocilizumab is given as a slow intravenous infusion of 400mg and the results will be compared with a similar group that does not receive the drug

##### Participants/Inclusion and exclusion criteria

1. Age range 70-18 years 2. p / f- Pao<sub>2</sub> / FIO<sub>2</sub> below 300 3. Negative IGRA test 4. IL-6 > 7 EXCLUSION: Acute or chronic renal failure liver cirrhosis Pregnancy latent TB Active gastric ulcer Dissatisfaction

##### Intervention groups

Patients receive Tocilizumab 400 mg diluted in 150 cc of normal saline in one hour as a single dose, and monitoring for oxygenation and complications in vital organs include : heart, kidneys, CNS, and disorders will be done. monitoring of hemodynamic and duration of mechanical ventilation and final mortality will be performed.

##### Main outcome variables

Tocilizumab, Pao<sub>2</sub>, P / F, and respiratory rate, invasive or non invasive mechanical ventilation, systolic blood pressure, urea creatinin , liver test impairment,

consciousness, coagulopathy, duration of MV and in hospital mortality

#### General information

##### Reason for update

##### Acronym

Tocilizumab

##### IRCT registration information

IRCT registration number: **IRCT20200406046968N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

##### Registration date

2020-04-14, 1399/01/26

##### Registrant information

##### Name

Haleh Mikaeili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3329 6024

##### Email address

halehmikaeili@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-21, 1399/02/02

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of IL-6 inhibitor (Tocilizumab) on the prognosis of covid-19 patients with acute respiratory failure

**Public title**  
The effect of IL-6 inhibitor (Tocilizumab) on the prognosis of covid-19 patients with acute respiratory failure hospitalized in Imam Reza Hospital in Tabriz

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age range 18-70 P/F<300 Negative IGRA test IL-6>7  
**Exclusion criteria:**  
Acute or chronic renal failure Increased liver enzymes 3 times normal with gastrointestinal symptoms or abdominal pain and nausea and jaundice or increased liver enzymes 5 times normal - liver cirrhosis Pregnancy latent TB Active gastric ulcer Dissatisfaction with entering the study

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **10**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Regional Ethics Committee in Research (Studies of Human Subjects), Tabriz University of Medical Scie

##### Street address

Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, Third Floor

##### City

Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614766

#### Approval date

2020-03-30, 1399/01/11

#### Ethics committee reference number

IR.TBZMED.REC.1399.010

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 disease

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19 disease

## Primary outcomes

### 1

#### Description

Percentage of effect of Tocilizumab on COVID-19 patients

#### Timepoint

Patients receive the drug in a single dose over an hour, and resorption monitoring will be performed to improve oxygenation status and subsequent complications in vital organs of the heart, kidneys, CNS, hemodynamic disturbances, duration of mechanical ventilation, and eventual mortality.

#### Method of measurement

Clinical and laboratory testing

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with COVID-19, in addition to the usual treatment, receive Tocilizumab IL-6 at a dose of 400 mg diluted in 155 cc of normal saline for one hour as a single dose, and monitoring is improved.

Oxygenation status and subsequent complications will occur in vital organs of the heart, kidneys, CNS, hemodynamic disturbances, duration of mechanical ventilation, and eventual mortality.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients with COVID-19 disease who have not received the Tocilizumab IL-6 medication are

routinely treated.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Mikaili, Haleh

**Street address**

Azadi St., Golgasht St., Imam Reza Hospital.

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imamreza@tbzmed.ac.ir

**Web page address**

<https://imamreza.tbzmed.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Adibkiya khosro

**Street address**

Azadi St., in front of Imam Reza Hospital, Central University Organization

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**Web page address**

<https://www.tbzmed.ac.ir/>

**Grant name**

Grant Call Corona Covid-19

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mikaili, haleh

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Others

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halehmikaeili@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mikaili, haleh

**Position**

Associate Professor

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Tabriz University of Medical Sciences

**Full name of responsible person**

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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**

COVID-19 disease can be fatal in cases that lead to hospitalization, and none of the protocol treatments prescribed in these patients are based on national guidelines and are not definitive. Supportive measures are especially important in the intensive care unit of these patients. In patients who enter this project, all the usual antiviral treatment measures are recommended and supportive measures will be taken in the intensive care unit, and patients will not be deprived of their continuation. Its pros and cons will be available to physicians and authorities for treatment

**When the data will become available and for how long**

1 month after analyzing the results

**To whom data/document is available**

For all researchers and physicians in the field of health

**Under which criteria data/document could be used**

In order to treat and its effective effects on the treatment and criteria of entry and exit of individuals

**From where data/document is obtainable**

Tabriz University of Medical Sciences website

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

Data access and its results will be freely accessible.

**Comments**