

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of The effect of Tocilizumab on the recovery rate of patients with severe Covid 19 disease referred to Razi Hospital in Ahvaz

#### Protocol summary

##### Study aim

Evaluation of the effect of tocilizumab on the recovery rate of patients with severe Covid 19 disease

##### Design

Single arm randomized clinical trial, without control group with a sample size of 15 people, phase 3 clinical trial

##### Settings and conduct

The place of the study is Razi Hospital in Ahvaz. Simple sampling of patients is done. It is a one-arm study and medicine is used

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: -Positive PCR test for covid- 19 - Hospitalization with pneumonia -Lung involvement in lung imaging -Oxygen saturation less than 90% -High levels of interleukin 6 -Not participating in another study  
Exclusion Criteria -Pregnant or lactating women -Severe liver disease -Allergic reaction to the used drugs - Neutrophils less than 500 -Platelets less than 50,000 - Intestinal diverticulosis or intestinal perforation - Positive viral markers or positive tuberculosis skin test

##### Intervention groups

This study is a single arm and has only one intervention group that receives Tocilizumab injection at a dose of 8 mg per kg and a maximum dose of 400 mg as a single dose

##### Main outcome variables

Mortality rate, Hospitalized in the intensive care unit, Number of days hospitalized in the intensive care unit, Interleukin 6

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210408050899N1**

Registration date: **2021-05-25, 1400/03/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

##### Registration date

2021-05-25, 1400/03/04

##### Registrant information

###### Name

Roohangize Nashibi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3333 5935

###### Email address

dr.r.nashibi@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-25, 1400/02/05

##### Expected recruitment end date

2021-05-31, 1400/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of The effect of Tocilizumab on the recovery rate of patients with severe Covid 19 disease referred to Razi Hospital in Ahvaz

##### Public title

Evaluation of The effect of tocilizumab on patients with severe Covid 19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Positive PCR test for COVID- 19 Oxygen saturation less than 90% Hospitalized with pneumonia High levels of interleukin 6 Not participating in another study

**Exclusion criteria:**

Pregnant or lactating women Severe liver disease (liver enzymes more than 5 times normal) Allergic reaction to the used drugs Neutrophils less than 500 Platelets less than 50000 Intestinal diverticulosis or intestinal perforation Positive viral markers or positive tuberculosis skin test

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

**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****1****Registry name****Secondary trial Id****Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical

**Street address**

Ethics committee, main building, Ahvaz University of medical science, Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6133744151

**Approval date**

2021-02-27, 1399/12/09

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

Covid\_19

**ICD-10 code**

U07.1

**ICD-10 code description**

Corona virus infection, unspecified

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

Mortality rate

**Timepoint**

End of study

**Method of measurement**

Patient file

**Secondary outcomes****1****Description**

Hospitalized in the intensive care unit

**Timepoint**

End of study

**Method of measurement**

Patient file

**2****Description**

Number of days hospitalized in the intensive care unit

**Timepoint**

End of study

**Method of measurement**

Patient file

**3****Description**

Interleukin 6

**Timepoint**

Before and after the intervention

**Method of measurement**

Measuring kit

**Intervention groups****1****Description**

Intervention group: Patients who continue to have low oxygen saturation despite receiving antiviral drugs and corticosteroids receive tocilizumab. The drug tocilizumab

made in China is Roche brand, which patients will receive at a dose of 8 mg per kilogram of body weight and a maximum dose of 400 mg as a single dose.

**Category**

Treatment - Drugs

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

Razi hospital, Ahvaz

**Full name of responsible person**

Rooh Angiz Nashibi

**Street address**

Razi hospital, Felestin Ave, Amanieh Ave

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6196514941

**Phone**

+98 61 3333 7446

**Email**

dr.r.nashibi@ajums.ac.ir

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mahdi Ahmadi moghadam

**Street address**

Main building, Ahvaz University of Medical Science, Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135539345

**Phone**

+98 61 3311 3815

**Email**

ahmadi-m@ajums.ac.ir

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Rooh Angiz Nashibi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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

Ahvaz University of Medical Sciences

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## Person responsible for updating data

### Contact

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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