

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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

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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

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

Name of organization / entity

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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