Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 tria

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
IR.AJUMS.REC.1399.936

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

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Ahvaz

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Khouzestan

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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Ahvaz

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6135539345

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+98 61 3311 3815

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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

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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