Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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- Pao2 / FIO2 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, Pao2, 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

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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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Valiasr St., Shariati St., East Kohanmooi St.

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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