Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of Tofacitinib drug (Iranian brand of Rhofanib drug) on clinical and laboratory symptoms in severe and resistant patients with COVID-19

Protocol summary

Study aim

Evaluation of the effect of Tofacitinib drug (Iranian brand of Rhofanib drug) on clinical and laboratory symptoms in severe and resistant patients with COVID-19

Design

This clinical trial study with control group, phase 3 is performed on 10 patients with severe disease initially. Patients are given 5 mg of Tofacitinib twice daily. If the patients' response to the drug is good during the study, the number of patients in the intervention group will be increased.

Settings and conduct

This study is performed in Firoozgar Hospital in Tehran and the patients are admitted to four ICU wards and two of these wards were considered for the intervention group and the other two for the control group. In the intervention group, Tofacitinib is given at a dose of 5 mg twice a day. Measurement of ferritin, LDH, D-dimer, IL-1, IL-2, IL-6 and TNF alpha will be performed and is repeated on the 14 day. On day one and 14, patients from both groups have a lung CT scan.Finally, statistical reviews and interpretation of information are performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patient satisfaction 2- Severe illness 3 - Leukocytes count above 3500 cells per micro liter and hemoglobin above 9 grams per deciliter of neutrophils above 1000 cells per microliter Exclusion criteria: 1- Pulmonary embolism or intravascular thrombosis 2- Active infection 3- Diverticulitis and gastric or intestinal ulcers 4 – Active Hepatitis B and hepatitis C and HIV infections 5- Active tuberculosis

Intervention groups

In this study, the intervention is tofacitinib and the intervention group is severe COVID-19 patients.The control group is similar to the intervention group but they are not given tofacitinib.

Main outcome variables

Oxygen saturation Number of breaths Heart rate Level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200531047619N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Simin Almasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8843 9678

Email address

almasi.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-21, 1399/05/31

Expected recruitment end date

2021-02-15, 1399/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Tofacitinib drug (Iranian brand of Rhofanib drug) on clinical and laboratory symptoms in severe and resistant patients with COVID-19

Public title

Evaluation of the effect of Tofacitinib in covid-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Severe illness (respiratory rate above 30 per minute, heart rate above 120 per minute and per cent reduction in peripheral oxygen saturation to less than 93%) Patients resistant to existing treatments

Exclusion criteria:

Bacterial infection is positive for the patient or procalcitonin is positive The patient may have hepatitis B or hepatitis C or HIV The patient has pulmonary embolism or intravascular thrombosis The patient has active and inactive tuberculosis The patient has diverticulitis and peptic ulcer Leukocytes count less than 3500 cells / mm and hemoglobin less than 9 g / dL and neutrophils less than 1000 cells / mm3

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

1-The dose of this drug in patients with rheumatoid arthritis is 5 mg twice a day and in patients with covid-19 the same dose is used for 10 days. 2-In this study, 10 patients are used first, and if the effect of the drug is good in improving patients, the number will be higher.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی ایران

Street address

Firoozgar Hospital, Valy-aser Avenue, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1593748711

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.IUMS.FMD.REC.1399.329

Health conditions studied

1

Description of health condition studied

Coronavirus disease (COVID-19)

ICD-10 code

U07.1.2

ICD-10 code description

An emergency ICD-10 code of ‘U07.1 COVID-19, virus identified’ is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing,An emergency ICD-10 code of ‘U07.2 COVID-19, virus not identified’ is assigned to a clinical or epidemiological d

Primary outcomes

1

Description

Oxygen saturation level

Timepoint

Daily

Method of measurement

Pulse oximetry

2

Description

Rate of breaths

Timepoint

Daily

Method of measurement

Number per minute

3

Description

Heart Rate

Timepoint

Daily

Method of measurement

Number per minute

4

Description
level of consciousness
Timepoint
Daily
Method of measurement
GCS, Glasgow Coma Scale

Secondary outcomes

1

Description
Radiographic changes in lung CT scan
Timepoint
The first and fourteenth day of treatment.
Method of measurement
Scoring system for determining the amount of grand glass and interstitial lung involvement (by radiologist)(By Radiologist)

2

Description
Measurement of serum levels of interleukin -1,interleukin- 2, interleukin-6 and TNF-alpha.
Timepoint
The first and fourteenth day of treatment.
Method of measurement
ELISA test

3

Description
Serum ferritin
Timepoint
The first and fourteenth day of treatment.
Method of measurement
Micro grams per liter

4

Description
D-dimer serum
Timepoint
The first and fourteenth day of treatment.
Method of measurement
Micro grams per milliliter

5

Description
hemoglobin
Timepoint
every other day
Method of measurement
gram per deciliter

6

Description
white blood cells count
Timepoint
every other day
Method of measurement
Micrograms per liter

7

Description
Platelet count
Timepoint
every other day
Method of measurement
Micro grams per liter

8

Description
Erythrocyte sedimentation rate
Timepoint
On the first, seventh and fourteenth days of treatment.
Method of measurement
Millimeter per hour

9

Description
Lactate dehydrogenase(LDH)
Timepoint
The first and fourteenth day of treatment.
Method of measurement
Micro grams per deciliter

Intervention groups

1

Description
Intervention group: This group includes severe and ill covid-19 patients who did not respond to routine and existing treatments.In these patients, the Iranian brand of drug tofacitinib or rhofanib is used and this drug is in the form of 5 mg tablets that are used orally twice a day for fourteen days and the manufacturer of this drug is Alvand Nanotechnology Company.
Category
Treatment - Drugs

2

Description
Control group: In this group, severe and ill COVID-19 patients are admitted to the ICU and received all the routine medications used in ill patients.Tofacitinib given in the intervention group is not given to the control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Simin Almasi
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Firoozgar hospital, Valadi Street, Valiasr Sq, Tehran, Iran
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Abbas Motavalian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran University of medical science
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
Iran University of Medical Sciences
Full name of responsible person
Simin Almasi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

Simin Almasi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

In this study, all data can be shared after identifying individuals.

When the data will become available and for how long

In this study, the data access time is six months after the results are published.

To whom data/document is available

The data of this study are available to researchers working in academic and scientific institutions and people working in industry.

Under which criteria data/document could be used

There is no limit to the use of this data and the only condition is that this data be used to advance science and help patients.

From where data/document is obtainable

For data, contact Simin Almasi at Firoozgar Hospital or email simin_almasi@yahoo.com.

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

About 7 to 10 days after the announcement of the request to obtain the data, this data will be received by the applicant.

Comments

I have no other explanation