

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 ground 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

Street address

Firoozgar hospital, Valadi Street, Valiasr Sq, Tehran, Iran

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Email

almasi.s@iums.ac.ir

Web page address

<http://firoozgar.iums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motavalian

Street address

Firoozgar hospital, Valadi Street, Valiasr Sq, Tehran, Iran

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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

Street address

Firoozgar hospital, Valadi Street, Valiasr Sq, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Simin Almasi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Simin Almasi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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