Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness evaluation of Tofacitinib plus Remdesivir in comparison with Remdesivir in the treatment of adult patients with severe COVID-19 A randomized double-blind placebo-included clinical trial

Protocol summary

Study aim

Study of Tofacitinib effectiveness in the treatment of sever COVID-19 patients

Design

Double-blind, randomized clinical trial with parallel control group, phase 2-3 on 60 patients. Sealed envelope web-page was used for randomization.

Settings and conduct

The study will be performed in the ICU of Razi Hospital in Rasht from March to June 2021. Sealed envelope web-page is used to allocate treatments to the two arms A and B. 60 patients will be placed in 15 blocks of 4. In intervention group (A) they will receive Tofacitinib 10 mg/day orally for 14 days + Remdesivir 100 mg/day intravenously and in control group (B) they will receive one placebo tablet/day orally for 14 days + Remdesivir 100 mg/day intravenously. Blinding type: Double-blinded. For this purpose an Intensive Care Fellowship prescribes the assigned codes to each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with severe Covid-19 admitted to the ICU of Razi Hospital in Rasht from March to June 2021. Exclusion criteria: Lack of informed consent; Lack of patient cooperation; Having active tuberculosis, hepatitis B or hepatitis C

Intervention groups

Intervention group: Tofacitinib oral tablet 10 mg daily + Remdesivir IV 100 mg daily for 14 days or hospital discharge (whichever comes first) Control group: Placebo oral tablet daily + Remdesivir IV 100 mg daily for 14 days or hospital discharge (whichever comes first)

Main outcome variables

The time required to improve clinical symptoms and paraclinical measures within 14 days of starting treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200329046892N2**
Registration date: **2021-03-09, 1399/12/19**
Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**
Update count: **0**

Registration date

2021-03-09, 1399/12/19

Registrant information

Name

Nematollah Ahangar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0099

Email address

n.ahangar@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-15, 1399/12/25

Expected recruitment end date

2021-06-15, 1400/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness evaluation of Tofacitinib plus Remdesivir in comparison with Remdesivir in the treatment of adult patients with severe COVID-19 A randomized double-blind placebo-included clinical trial

Public title
Effect of tofacitinib in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with severe Covid-19 admitted to the ICU of Razi Hospital in Rasht for period of March- June 2021 Age greater than or equal to 18 years Patients admitted with the following criteria: fever (oral temperature greater than 37.2 ° C), dry cough, severe tiredness or dyspnea At least one of the following criteria : positive PCR OR lung involvement on chest X-ray / CT scan Absolute lymphocyte count greater than or equal to 200 per cubic millimeter Absolute neutrophil count greater than or equal to 1000 per milliliter Cubic meters Hemoglobin above 8 grams per deciliter

Exclusion criteria:
Lack of informed consent Lack of patient cooperation Having pulmonary embolism or intravascular thrombosis Having another active infection Having diverticulitis and gastric ulcer Having tuberculosis or hepatitis B or active hepatitis C or HIV Any major drug interaction between routine patient's drugs with any of the study drugs Pregnancy and lactation Simultaneous presence in other research study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
It is a block randomization type and the block with size of 4. Randomization tool: sealedenvelope.com. 60 patients will be assigned in 15 blocks of 4. In intervention group (A) they will receive Tofacitinib 10 mg/day orally for 14 days + Remdesivir 100 mg/day intravenously and in control group (B) they will receive one placebo tablet/day orally for 14 days + Remdesivir 100 mg/day intravenously. Concealment is done using the sealed envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants (patients) and medical staff are kept blind to the specificity of study groups (Double-blinded). For this purpose, an independent person from the research team and an Intensive Care Fellowship prescribes the assigned codes to each patient. To ensure the similarity between the drug and the placebo, the placebo is made by the same company. Study drugs will be placed in similar packages, and patients will receive pre-arranged interventions in the order in which they enter the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
School of Medicine, Guilan University Complex, 7th Km Tehran Road

City
Rasht

Province
Guilan

Postal code
4199613769

Approval date
2021-03-04, 1399/12/14

Ethics committee reference number
IR.GUMS.REC.1399.630

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
virus identified

2

Description of health condition studied
COVID-19

ICD-10 code
U07.2

ICD-10 code description
virus not identified; Clinically-epidemiologically diagnosed COVID-19; Probable COVID-19; Suspected COVID-19

Primary outcomes

1

Description
The time required to improve clinical symptoms and within 14 days of treatment start
Timepoint
Daily from the first day of intervention
Method of measurement
Physical examination

Secondary outcomes

1

Description
Body temperature
Timepoint
Daily from the first day of intervention
Method of measurement
Thermometer

2

Description
Heart rate
Timepoint
Daily from the first day of intervention
Method of measurement
Pulse oxymeter

3

Description
Pulmonary radiological state
Timepoint
Weekly
Method of measurement
CT scan

4

Description
Blood pressure
Timepoint
Daily from the first day of intervention
Method of measurement
Barometer

5

Description
Mechanical ventilation
Timepoint
Daily from the first day of intervention
Method of measurement
Physical examination

6

Description
Duration of hospitalization in the intensive care unit
Timepoint
Daily from the first day of intervention
Method of measurement
Record in the patient file

7

Description
Mortality
Timepoint
Daily from the first day of intervention
Method of measurement
Record in the patient file

8

Description
Respiration rate
Timepoint
Daily from the first day of intervention
Method of measurement
Count

9

Description
Intubation
Timepoint
Daily from the first day of intervention
Method of measurement
Physical examination

10

Description
SPO2
Timepoint
Daily from the first day of intervention
Method of measurement
Pulse-oxy meter

11

Description
D-Dimer
Timepoint
Every 3 days from the first day of intervention
Method of measurement
Fluorescence immunochromatography

12

Description
Creatine phosphokinase
Timepoint
Every 3 days from the first day of intervention
Method of measurement
International Federation of Clinical Chemistry (IFCC)

13

Description
C reactive protein
Timepoint

Every 3 days from the first day of intervention

Method of measurement

Turbidometry

14

Description

Erythrocyte sedimentation rate

Timepoint

Every 3 days from the first day of intervention

Method of measurement

Westergren method

15

Description

Ferritin

Timepoint

Every 3 days from the first day of intervention

Method of measurement

Chemiluminescence method

Intervention groups

1

Description

Intervention group: Tofacitinib10 mg (Rofanib, Nano Alvand) 1 oral tablet daily + Remdesivir IV 100 mg daily for 14 days or hospital discharge (whichever comes first)

Category

Treatment - Drugs

2

Description

Control group: Placebo (Nano Alvand daru) 1 oral tablet daily + Remdesivir IV 100 mg daily for 14 days or hospital discharge (whichever comes first)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Mohammad Haghighi

Street address

Sardar Jangal Ave.

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Province

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4199613769

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

Street address

Shahid Siadati Ave.. Namju St.

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research@gums.ac.ir

Web page address

https://www.gums.ac.ir/research

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Nematollah Ahangar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for scientific inquiries

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Rasht University of Medical Sciences
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Nematollah Ahangar
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
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
Title and more details about the data/document
Data about primary outcome
When the data will become available and for how long
1 month after results publish
To whom data/document is available
Researchers
Under which criteria data/document could be used
Requested by authenticated scientific centers and universities
From where data/document is obtainable
Dr. Nematollah Ahangar School of Medicine Email: n.ahangar@gums.ac.ir
What processes are involved for a request to access data/document
Official request signed by highest executive is mandatory. Moreover, acceptable reasons should be noted
Comments