

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 severe 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.

**City**

Rasht

**Province**

Guilan

**Postal code**

4199613769

**Phone**

+98 13 3354 1001

**Email**

manesthesist@gmail.com

**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.

**City**

Rasht

**Province**

Guilan

**Postal code**

4144666949

**Phone**

+98 13 3333 6394

**Email**

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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School of Medicine, Guilan University Complex, 7th Km Tehran road

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**Province**

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41996-13769

**Phone**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Nematollah Ahangar

**Position**

Associate Professor

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**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Nematollah Ahangar

**Position**

Associate Professor

**Latest degree**

Ph.D.

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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**