Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of Tofacitinib/Remdesivir combination therapy compared to Remdesivir treatment on clinical status and laboratory findings of patients with severe Covid-19: A double-blind randomized clinical trial study

Protocol summary

Study aim

Determining the efficacy of Tofacitinib/Remdesivir combination therapy compared to Remdesivir treatment on clinical status and laboratory findings of patients with severe Covid-19

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized block, phase 2-3 on 48 patients. Random chains and concealment codes were produced by the website "www.sealedenvelope.com".

Settings and conduct

This double-blind randomized study is performed in Razi Hospital, Ahvaz. Participants and researchers in this study will be blind to the specificity of study groups. Group 1 receives Tofacitinib at a dose of 10 mg twice daily (for 5 days) in addition to the 5-day course of Remdesivir. Group 2 will also receive Tofacitinib at a dose of 10 mg twice daily (for 5 days) along with a 10-day course of remediation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Conscious willingness and written consent to participate in the study; Age 18 years or older; Hospitalization; Severity of the disease; Positive polymerase chain reaction (PCR) test; Lung involvement based on CT scan

Intervention groups

Intervention group: Group 1 receives Tofacitinib at a dose of 10 mg twice daily (for 5 days) in addition to the 5-day course of Remdesivir. Group 2 will also receive Tofacitinib at a dose of 10 mg twice daily (for 5 days) along with a 10-day course of remediation. Control group: Group 3 receives a 5-day course of Remdesivir with a placebo that will be given twice daily for 5 days. Group 4 also receives a 10-day course of Remdesivir with a placebo, which will be given twice a day for 5 days.

Main outcome variables

Number of breaths; Percentage of oxygen saturation; Performance status; State of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200426047212N2**
Registration date: **2021-11-11, 1400/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-11, 1400/08/20**
Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Ali Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 7153

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hatami_a@shoushtarums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Tofacitinib/Remdesivir combination therapy compared to Remdesivir treatment on clinical status and laboratory findings of patients with severe Covid-19: A double-blind randomized clinical trial study

Public title

Effect of Tofacitinib in treatment of Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

informed written desire and consent to participate in the study Age 18 years or older Hospitalization Severe disease Positive polymerase chain reaction (PCR) test Lung involvement based on CT scan

Exclusion criteria:

Death of the patient Physician's diagnosis of not participating in the study History of thrombosis or current thrombosis Suppression of the known immune system Pregnancy and lactation Use of angiotensin converting inhibitors Severe renal, hepatic, respiratory and cardiovascular insufficiency Consumption of cytotoxic drugs Transfer to another hospital

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of samples to each of the intervention and control groups will be done by random block method and using 4 blocks. Random chains and concealment codes will be generated by www.sealedenvelope.com. To hide the random chain, the method of envelopes in opaque packages is also used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers in this study are blinded to the specialization of study groups, and an independent person from the research team, along with the Intensive Care Fellowship, prescribes the assigned codes to each patient. To ensure the similarity between the drug and the placebo, the placebo will be made by the same drug company and the study drugs will be placed in similar envelopes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.AJUMS.REC.1400.415

Health conditions studied

1

Description of health condition studied

Coronavirus

ICD-10 code

U07. 1

ICD-10 code description

COVID19, virus identified

Primary outcomes

1

Description

Lactate Dehydrogenase

Timepoint

Before the intervention and one day after the intervention

Method of measurement

Venous blood test

2

Description

Blood Urea Nitrogen

Timepoint

Before the intervention and one day after the

intervention
Method of measurement
Venous blood test

3

Description
Creatinine
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

4

Description
Alanine Aminotransferease
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

5

Description
Aspartate Aminotransferase
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

6

Description
Alkaline Phosphatase
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

7

Description
C-Reactive Protein
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

8

Description
White Blood Cell
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

9

Description
Neutrophil
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

10

Description
lymphocytus
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

11

Description
Red Blood Count
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

12

Description
Erythrocyte Sedimentation Rate
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Venous blood test

Secondary outcomes

1

Description
Respiratory Rate
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Count the respiratory rate per minute

2

Description
Percentage of oxygen saturation
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Pulse oximeter

3

Description
Heart Rate
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Count the number of heart pumps per minute

4

Description
Systolic blood pressure
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Calculate the pressure when the heart contracts

5

Description
Body temperature
Timepoint
Before the intervention and one day after the intervention
Method of measurement
Based on thermometer

6

Description
Performance status
Timepoint
Before the intervention and one day after the intervention
Method of measurement
According to PRIEST checklist

7

Description
State of consciousness
Timepoint
Before the intervention and one day after the intervention
Method of measurement
According to PRIEST checklist

Intervention groups

1

Description
Intervention group: Depending on the response to treatment, group 1 will receive Tofacitinib at a dose of 10 mg twice daily (for 5 days) in addition to the 5-day course of Remdesivir (Administration of 200 mg of Remdesivir on the first day and then 100 mg intravenously four days later). Group 2, depending on the response to treatment, will receive Tofacitinib at a dose of 10 mg twice daily (for 5 days) along with a 10-day course of Remdesivir (Administration of 200 mg of Remdesivir on the first day and then 100 mg intravenously on the next nine days) .
Category
Treatment - Drugs

2

Description
Control group: Group 3, depending on the response to treatment, receives a 5-day course of Remdesivir (Administration of 200 mg of Remdesivir on the first day and then 100 mg intravenously four days later) with placebo, which will be given twice a day for 5 days. Group 4 will also receive a 10-day Remdesivir course (Administration of 200 mg of Remdesivir on the first day and then 100 mg intravenously on the next nine days) with a placebo that will be given twice daily for 5 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Reza Khedri
Street address
Razi Hospital, Felestin Ave., Ahvaz, Amanieh Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
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Ground floor, Deputy of Research and Technology Building, Ahvaz Jundishapur University of Medical Sciences, Golestan St.
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Web page address
https://vchresearch.ajums.ac.ir/en-US/vchresearch.ajums.ac/5233/page/Deputy-of-Research-and-Technology-Development

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mehrdad Dargahi-Malamir

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pulmonologist

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available