Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Efficacy of standard treatment and dimethyl fumarate in the treatment of patients with COVID-19

Protocol summary

Study aim
This study will be performed to determine the efficacy of dimethyl fumarate versus standard therapy in treating hospitalized patients with COVID-19.

Design
A two-arm, parallel, randomized, double-blind, controlled clinical trial on 30 hospitalized COVID-19 patients. Random blocks will be used for randomization.

Settings and conduct
This study will be performed on hospitalized COVID-19 patients in Ayatollah Rouhani hospital under the supervision of infectious disease specialists and pulmonologists. After confirming the disease with a chest CT scan or RT-PCR test and checking the inclusion criteria, patients will be randomly assigned to one of the two groups. This study is designed as a double-blind study.

Participants/Inclusion and exclusion criteria
Summary of inclusion criteria: both sexes, aged > 18 years, confirmation of COVID-19 infection by RT-PCR, need to be hospitalized, no need for mechanical ventilation, the amount of supplemental oxygen flow by each device more than 10 do not exceed 10 L/min. Summary of exclusion criteria: pregnant or lactating women, history of dimethyl fumarate allergy, history of dimethyl fumarate use in previous hospitalizations, liver function tests> 5 ULN, estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m2 using the MDRD equation

Intervention groups
Patients will be divided into control (placebo + national standard treatment) and intervention groups (dimethyl fumarate + national standard treatment).

Main outcome variables
Need for mechanical ventilation; Death

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201024049134N4**
Registration date: **2021-10-21, 1400/07/29**
Registration timing: **prospective**

Last update: **2021-10-21, 1400/07/29**
Update count: **0**

Registration date
2021-10-21, 1400/07/29

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-20, 1400/08/29

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Efficacy of standard treatment and dimethyl fumarate in the treatment of patients with COVID-19

Public title
The Efficacy of dimethyl fumarate in the treatment of patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women of at least 18 years of age capable of providing informed consent Confirmation of COVID-19 with RT-PCR Need for hospitalization No need for mechanical ventilation No need to more than 10 L/min of supplemental oxygen by any device. The patient must meet at least one of the following high-risk criteria: age 70 years or older, obesity (BMI ≥ 30 kg/m2), diabetes mellitus, uncontrolled blood pressure (systolic blood pressure> 150 mm Hg), history of respiratory disease (Including asthma or COPD), history of heart failure, history of coronary artery disease, fever > 38.4°C in the last 48 hours, shortness of breath at the time of referral, Bicytopenia, Pancytopenia, or a combination of neutrophilia and lymphopenia

Exclusion criteria:
History of allergy to dimethyl fumarate Use of dimethyl fumarate before current hospitalization Patients more than 70 years of age with a history of any of the following in the last six months: Class III / IV Heart Failure Based on the New York Heart Association (NYHA) classification, Insulin-dependent diabetes, Angina pectoris, Malignancy Uncontrolled bacterial, fungal, or viral infection (other than COVID-19). Any history of receiving convalescent plasma therapy Absolute neutrophil count (ANC) < 500 Platelets count < 50,000 Pregnant women or those intending to become pregnant Breastfeeding women AST or ALT > 5 times the upper limits of normal (ULN) Estimated glomerular filtration rate (eGFR) < 30 ml/min in 1.73 m2 using MDRD equation

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Unit randomization is done by block method with a block size of 4. For each of the 6 possible scenarios for the quadruple block, the numbers are assigned as follows AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6). With the help of a dice, the numbers between 1 and 6 are selected, and the treatment allocation list is determined according to each number. To execute the generated random sequence, the method of hiding coded boxes or cans is used. In this method, the cans are numbered in a random sequence. Inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written is provided to the executor with the condition that the boxes are completely sealed. Finally, the researcher assigns patients to the standard intervention and treatment group based on patients' admission orders. Tools: Create random sequences of 4 random blocks Concealment to execute random sequences on study participants will be done. How to make blocks: Randomly select the block and read the letters from right to left. Hiding will be done by the method of cans that are numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants (patients), clinical caregivers, and a group of researchers in charge of implementing the protocol will be blinded. Due to the similar appearance and use of the drug under study and placebo, these people can not distinguish them.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Babol University of Medical Sciences

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GanjAfrooz Blvd.

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Approval date
2021-10-04, 1400/07/12

Ethics committee reference number
IR.MUBABOL.REC.1400.221

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Need for mechanical ventilation
Timepoint
30 days after the start of the intervention
Method of measurement
Examination of the patients by the research team

2

Description
Death
Timepoint
30 days after the start of the intervention
Method of measurement
Examination of the patients by the research team

3

Description
Severely ill
Timepoint
30 days after the start of the intervention
Method of measurement
Examination of the patients by the research team

Secondary outcomes

1

Description
Cessation of fever
Timepoint
30 days after the start of the intervention
Method of measurement
Examination of the patients by the research team

2

Description
Improve ESR, CRP, and CBC test results
Timepoint
30 days after the start of the intervention
Method of measurement
Interpretation of paraclinical tests' results

3

Description
Negative RT-PCR test
Timepoint
30 days after the start of the intervention
Method of measurement
RT-PCR test

4

Description
Improve oxygen saturation
Timepoint
30 days after the start of the intervention
Method of measurement
Pulse oximeter

5

Description
Improve pulmonary involvement on CT scan
Timepoint
30 days after the start of the intervention
Method of measurement
Chest CT scan

Intervention groups

1

Description
Control group: Patients in this group receive placebo capsules (capsules containing wheat flour) daily for 5 days (a total of 5 capsules per patient). Also, in this group, in addition to placebo capsules, people will be prescribed drugs listed in the national protocol for treating hospitalized patients with Covid-19 (including corticosteroids and remdesivir).
Category
Placebo

2

Description
Intervention group: Patients in this group receive dimethyl fumarate 240 mg capsules (CinnaGen, Tehran, Iran) daily for 5 days (a total of 5 capsules per patient). Also, in this group, in addition to dimethyl fumarate capsules, the drugs listed in the national protocol for treating hospitalized patients with Covid-19 (including corticosteroids and remdesivir) will be administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
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1

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Grant name
Grant code / Reference number
140012514
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All participants' personal data can be shared after the anonymization of individuals.

When the data will become available and for how long

Six months after the end of the study and publication of the article

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no specific preconditions.

From where data/document is obtainable

They should send their request to the person in charge of the study, Dr. Mostafa Javanian, with the e-mail address: mjavanian@gmail.com

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

On average, it will take two weeks to process the application.

Comments