

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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 \geq 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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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

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
A Level or less

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

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