# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Efficacy of colchicine in patients with COVID-19 infection: A randomized, single-blind, placebo-controlled clinical trial

### Protocol summary

**Study aim**

This study will be performed to determine the efficacy of colchicine versus placebo in the treatment of outpatients with COVID-19.

**Design**

A two-arm, parallel, randomized, single-blind, controlled clinical trial on 500 COVID-19 outpatients. Random blocks will be used for randomization.

**Settings and conduct**

This study will be performed on outpatients with COVID-19 in an outpatient clinic under infectious disease specialists' supervision. After confirming the disease with the RT-PCR test and meeting the inclusion criteria, they will be randomly assigned to one of the two groups. Also, the participants will be blinded.

**Participants/Inclusion and exclusion criteria**

Patients with the new coronavirus infection 2019 (COVID-19) confirmed by the RT-PCR test with the approval of an infectious disease specialist and an indication for outpatient treatment status (do not have any of the following): PaO2/FiO2 < 300, SpO2 < 93%, Respiratory rate > 30, Progressive lung involvements in CT scan The patient must meet at least one of the following high-risk criteria: 70 years of age or older, obesity (BMI ≥ 30 kg/m2), diabetes, uncontrolled blood pressure (systolic blood pressure > 150 mm Hg), known case of respiratory disease (Including asthma or COPD), known case of heart failure, known case of coronary artery disease, fever > 38.4°C in the last 48 hours, shortness of breath at the time of enrollment, Bicytopenia, Pancytopenia or a combination of neutrophilia and lymphopenia.

**Intervention groups**

The control group will receive placebo tablet BID for the first three days, then QD for the next 27 days. The intervention group will receive colchicine 0.5 mg tablet BID for the first three days, then QD for the next 27 days.

**Main outcome variables**

1) Require hospitalization 2) Death

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201024049134N3**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

**Registration date**

2021-06-21, 1400/03/31

**Registrant information**

**Name**

Mohammad Barary

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-06-22, 1400/04/01

**Expected recruitment end date**

2021-12-22, 1400/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of colchicine in patients with COVID-19 infection: A randomized, single-blind, placebo-controlled clinical trial

**Public title**

Efficacy of colchicine in the treatment of COVID-19 patients

**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 in the last 24 hours Patients with outpatient treatment status (do not have any of the following): PaO2/FiO2 < 300, SpO2 < 93%, Respiratory rate > 30, Progressive lung involvements in CT scan The patient must meet at least one of the following high-risk criteria: 70 years of age or older, obesity (BMI ≥ 30 kg/m2), diabetes, uncontrolled blood pressure (systolic blood pressure > 150 mm Hg), known case of respiratory disease (Including asthma or COPD), known case of heart failure, known case of coronary artery disease, fever > 38.4°C in the last 48 hours, shortness of breath at the time of enrollment, Bicytopenia, Pancytopenia or a combination of neutrophilia and lymphopenia

**Exclusion criteria:**

The patient is currently hospitalized or needs immediate care and hospitalization. Showing any symptoms of shock or hemodynamic instability. History of inflammatory bowel disease (Crohn's disease or ulcerative colitis), chronic diarrhea or malabsorption. History of progressive neuromuscular disease. Estimated glomerular filtration rate (eGFR) < 30 ml/min in 1.73 m2 using MDRD equation. History of cirrhosis, chronic active hepatitis or severe liver disease. Pregnant, breastfeeding, or women Intending to get pregnant during the study period or 6 months after the last dose of study agent. History of colchicine use for other conditions, including Familial Mediterranean Fever or gout. History of allergic reaction or severe sensitivity to colchicine. Cancer patients undergoing active chemotherapy.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **500**

**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)**

Single blinded

**Blinding description**

In this study, patients will be blinded. However, due to the similar appearance and injection method of the drug and placebo, the patient can not know which one he/she received.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee of Babol University of Medical Sciences

**Street address**

GanjAfrooz Blvd.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Approval date**

2021-05-31, 1400/03/10

**Ethics committee reference number**

IR.MUBABOL.REC.1400.125

## 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**
Require hospitalization
**Timepoint**
30 days after the start of the intervention
**Method of measurement**
Examination of the patients by the research team

### 2

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

### 3

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

## Secondary outcomes

### 1

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

### 2

**Description**
Incidence of severe complications, such as pulmonary fibrosis, prolonged illness, or malaise
**Timepoint**
30 days after the start of the intervention
**Method of measurement**
Examination of the patients by the research team

## Intervention groups

### 1

**Description**
Control group: Patients in this group receive placebo tablets (containing oral calcium chloride, Caspian Pharmaceutical Company, Iran) for the first 3 days, twice a day, and then for the next 27 days, once a day. In addition to placebo, these participants will be prescribed the drugs listed in the National Covid-19 Treatment Protocol (including famotidine, cetirizine, N-acetylcysteine, bromhexine, naproxen, and fluticasone spray ).
**Category**
Placebo

### 2

**Description**
Intervention group: Colchicine 0.5 mg tablets for the first 3 days, twice a day, and then for the next 27 days, once a day. In this group, in addition to colchicine, people will be prescribed drugs listed in the national protocol for the treatment of Covid-19 disease (including famotidine, cetirizine, N-acetylcysteine, bromhexine, naproxen, and fluticasone spray ).
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rouhani hospital outpatient clinic
**Full name of responsible person**
Masumeh Bayani
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## Sponsors / Funding sources

### 1

**Sponsor**
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**Web page address**
http://research.mubabol.ac.ir/about/?id=350

**Grant name**

**Grant code / Reference number**
140012019

**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**
Mohammad Barary
**Position**
Medical student
**Latest degree**
A Level or less
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**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. Masumeh Bayani, with the e-mail address: m_baiany@yahoo.com.

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

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

**Comments**