Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

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
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Sponsors / Funding sources

1

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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
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Full name of responsible person
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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