

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

Investigation of the efficacy and safety of colchicine In combination with standard treatment on covid-19 patients: A clinical trial

Protocol summary

Study aim

Evaluation of the efficacy and safety of colchicine in combination with standard treatment in patients with covid 19

Design

Clinical trial with control group, with parallel, double blind and randomized groups

Settings and conduct

This is a prospective, double-blind, randomized controlled clinical trial, and the patient, physician and evaluator will be unaware of all steps

Participants/Inclusion and exclusion criteria

Entry: Age 18 to 70 years; Detection of COVID-19 in the last 24 to 48 hours; $o_2sat < 93\%$ or $RR > 24$ or $Pao_2 / Fio_2 < 300$; Covid-19 patients hospitalized with hospital indications according to the guideline of the country that has pulmonary infiltration in CT scan; No consumption colchicine during the last week ;Exclusion: Patients with a history of chronic Crohn's or colitis, diarrhea, or chronic malabsorption; History of cirrhosis, hepatitis and severe liver disease; Patients currently taking colchicine for other uses, such as gout or Mediterranean fever; Patients with a history of allergic reactions or allergies to colchicine; Patients receiving chemotherapy for cancer

Intervention groups

Patients in the Colchicine group take half a milligram a day for one to three days, and one milligram a day for the next 12 days in addition to standard treatment, patients in the control group take standard treatment

Main outcome variables

clinical symptoms including fever, cough, shortness of breath; laboratory symptoms (ESR, CRP, NLR, LDH, ferritin, D-dimer, CBC diff); o_2sat at the time of hospitalization and discharge; finding of pulmonary infiltration in CT scan

General information

Reason for update

Registration of the second center according to the nationality of the project Remove the placebo

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N5**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-12, 1400/01/23**

Update count: **1**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Fatemeh Saghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2021-02-04, 1399/11/16

Actual recruitment start date

2020-03-26, 1399/01/07

Actual recruitment end date

2020-12-30, 1399/10/10

Trial completion date

2021-01-14, 1399/10/25

Scientific title

Investigation of the efficacy and safety of colchicine In

combination with standard treatment on covid-19 patients: A clinical trial

Public title
Effect of colchicine in treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
- Age 18 to 70 years - Detection of COVID-19 in the last 24 to 48 hours - Candidate for hospitalization (o2sat <93% or RR> 24 or Pao2 / Fio2 <300) - COVID-19 patients hospitalized with hospital indications according to the guideline of the country that has pulmonary infiltration in CT scan -Not being pregnant and not becoming pregnant until 30 days after the end of the study - No consumption of colchicine during the last week (due to the half-life of 20-40 hours of the drug) - Outpatients with pulmonary infiltration on CT scan
Exclusion criteria:
Patients with a history of Crohn or Ulcerative colitis, diarrhea, or chronic malabsorption Neuromuscular diseases GFR less than 30 ml per minute History of cirrhosis, hepatitis and severe liver disease Patients receiving chemotherapy for cancer Patients currently taking colchicine for other uses, such as gout or Mediterranean fever Patients with a history of allergic reactions or allergies to colchicine Pregnancy and lactation

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**
Actual sample size reached: **152**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of the study, patients will be assigned to one of the two divided groups with a random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
All stages will be covered by the patient, the treating physician and the evaluators. In this way, the first executor of the sequence plan specifies the allocation of people according to the order of admission of sick people to the study and pours the drugs into one-packets for consumption for two weeks and identifies them with A or B codes. Then, the drugs suitable for each person are identified according to the above explanations and placed in special envelopes and delivered to patients. One group is given a placebo and standard treatment and the other group is given a colchicine and standard treatment.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee for Ethics in Biomedical Research
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran
City
tehran
Province
Tehran
Postal code
8915173143
Approval date
2020-04-02, 1399/01/14
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.018

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
-Clinical symptoms including fever, cough, shortness of breath
Timepoint
The first, third, seventh, fourteenth and 6-8 days after entering the study
Method of measurement
questionnaire

2

Description
pulmonary infiltration findings on CT scan
Timepoint
Two weeks later and 6-8 weeks later
Method of measurement

CT-scan

3

Description

o2sat at the time of hospitalization and discharge

Timepoint

The first, third, seventh, fourteenth and 6-8 days after entering the study

Method of measurement

Pulse Oximeter

4

Description

Laboratory symptoms (ESR, CRP, NLR, LDH, ferritin, D-dimer, CBC diff)

Timepoint

Hospitalization time and discharge time

Method of measurement

Blood test

Secondary outcomes

1

Description

Need hospitalization in icu

Timepoint

The first, third, seventh, fourteenth and 6-8 days after entering the study

Method of measurement

questionnaire

2

Description

Mortality

Timepoint

The first, third, seventh, fourteenth and 6-8 days after entering the study

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Receive 0.5 mg of colchicine until the third day and 12 days later one mg plus standard treatment including 200 mg hydroxychloroquine daily

Category

Treatment - Drugs

2

Description

Control group: From the first to the third day, two tablets of placebo and for the next 12 days, one daily dose in addition to the standard treatment (200 mg hydroxychloroquine daily).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoghi Hospital

Full name of responsible person

Nadia Soltani gerdefaramarzi

Street address

Yazd, Shahid Ghandi Blvd., Ibn Sina St., Shahid Sadoughi Hospital

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<https://web.ssu.ac.ir/index.aspx?lang=1&sub=16>

2

Recruitment center

Name of recruitment center

NRITLD. Masih daneshvari hospital

Full name of responsible person

Guitti Pourdowlat

Street address

Masih daneshvari hospital, shahid bahonar ave. tehran. Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Nadia Soltani Gerdefaramarzi
Position
University student
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A Level or less
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Person responsible for updating data

Contact
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A Level or less
Other areas of specialty/work
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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

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