Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of colchicine in the incidence of pulmonary complications after COVID-19 infection: a randomized clinical trial

Protocol summary

Study aim
Determining the effectiveness of colchicine in improving pulmonary fibrosis and preventing bronchiectasis/cavitary lesions/air retention lesions and bronchitis after COVID-19 compared to the control group

Design
Clinical trial work with a control group without blinding, randomized, phase 3 on 100 patients The method of randomization will be that by using the table of random numbers created on the online site, patients will be assigned to 2 groups, and the method of allocation will be by using envelopes in bed.

Settings and conduct
The way of entering the patients into the study is random and the patients referred to Vasi Hospital who have been diagnosed with Covid-19 will be divided into 2 groups. A group of patients who were prescribed colchicine by a doctor are compared with the control group, which are patients who were not prescribed colchicine by other doctors.

Participants/Inclusion and exclusion criteria
Eligibility criteria: Patients who have been clinically, radiologically and PCR confirmed to have COVID-19 Age above 18 years Informed written consent Exit criteria during the study: Cases of colchicine contraindications and cases that do not meet the above criteria

Intervention groups
In the intervention group, after recovering from the acute phase, they will receive colchicine 0.5 mg twice a day for a period of one month. After the 3-month period, lung CT scan will be performed to investigate post-covid pulmonary complications, and the variables of pulmonary fibrosis, cavitary lesions, bronchitis, bronchiectasis, and air trapping lesions will be evaluated and quantitatively compared in terms of the number of involved lobes in both groups.

Main outcome variables
Pulmonary fibrosis; bronchitis; bronchiectasis; cavitary lesions; Air retention lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251112067972N1**
Registration date: **2026-04-23, 1405/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-23, 1405/02/03**
Update count: **0**

Registration date
2026-04-23, 1405/02/03

Registrant information

Name
Fateme Alizadeh moosavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4465 1300

Email address
alizademoosavif01@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-26, 1404/11/06

Expected recruitment end date
2026-05-20, 1405/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of colchicine in the incidence of pulmonary complications after COVID-19 infection: a randomized clinical trial

Public title
The effect of colchicine in patients with covid 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have been clinically, radiologically and PCR confirmed to have COVID-19 Age above 18 years Informed written consent
Exclusion criteria:
History of hypersensitivity to colchicine Pregnancy or lactation Patients with severe renal impairment (creatinine clearance [CrCl] < 30 mL/min) Patients with severe hepatic impairment (AST or ALT > 5 times the upper limit of normal [ULN]) Patients with hematologic dyscrasias, absolute neutrophil count < 1,000/mm³ or platelet count < 50,000/mm³ Patients with a history of severe heart failure Severe diarrhea, diverticulitis, or bowel perforation Patients unable to tolerate oral intake Patient demise Concomitant use of medications with contraindications to colchicine
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization will be that by using the table of random numbers created on the online site, the patients will be assigned to 2 groups and the method of allocation will be using envelopes in bed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of sabzevar University of Medical Sciences
Street address
Sabzevar, Shohadaye Hasteiee Boulevard, Sabzevar University of Medical Science
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873137
Approval date
2025-03-09, 1403/12/19
Ethics committee reference number
IR.MEDSAB.REC.1403.188

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.1+J12.
ICD-10 code description
COVID-19, virus identified /Other viral pneumonia

Primary outcomes

1

Description
Investigating changes in pulmonary fibrosis in CT scan of patients with covid-19
Timepoint
CT scan evaluation of patients' lungs 3 months later
Method of measurement
Investigation of lesions in lung CT scan

2

Description
Investigating changes in pulmonary bronchiectasis in CT scan of patients with covid-19
Timepoint
CT scan evaluation of patients' lungs 3 months later
Method of measurement
Investigation of lesions in lung CT scan

3

Description
Investigating changes in bronchitis in CT scan of patients with covid-19
Timepoint
CT scan evaluation of patients' lungs 3 months later
Method of measurement
Investigation of lesions in lung CT scan

4

Description
Investigating changes in cavitary lesions and air

retention in CT scan of patients with covid-19

Timepoint

CT scan evaluation of patients' lungs 3 months later

Method of measurement

Investigation of lesions in lung CT scan

5

Description

Investigating changes in air retention in CT scan of patients with covid-19

Timepoint

CT scan evaluation of patients' lungs 3 months later

Method of measurement

Investigation of lesions in lung CT scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after recovering from the acute phase, they will receive colchicine 0.5 mg twice a day for a period of one month. After the 3-month period, lung CT scan will be performed to investigate post-covid pulmonary complications, and the variables of pulmonary fibrosis, cavitary lesions, bronchitis, bronchiectasis and air trapping lesions will be evaluated and quantitatively compared in terms of the number of involved lobes in both groups.

Category

Treatment - Drugs

2

Description

Control group: In the control group, after recovering from the acute phase, they will receive placebo twice a day for a period of one month. After the 3-month period, lung CT scan will be performed to investigate post-covid pulmonary complications, and the variables of pulmonary fibrosis, cavitary lesions, bronchitis, bronchiectasis and air trapping lesions will be evaluated and quantitatively compared in terms of the number of involved lobes in both groups.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Fateme Alizadeh Mousavi

Street address

Sabzevar, Tohid Shahr Blvd., Vasi Medical Education Center

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9617913112

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Email

waseehospital@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research and technology

Full name of responsible person

Dr.Seyed Alireza Javadinia

Street address

Above the Tomb of Anonymous Martyrs, University Campus Building, Tawheed Shahr Blvd.,

City

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9613873136

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Email

M.S@medsab.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

vice chancellor for research and technology

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

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Alizadeh moosavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Vasei hospital; touhid shahr blvd;sabzevar town

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AlizademoosaviF01@medsab.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Alizadeh moosavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Vasei hospital; touhid shahr blvd;sabzevar town

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Alizadeh moosavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

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Province

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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