

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 Saghafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 3419

##### Email address

f.saghafi@ssu.ac.ir

##### 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

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

8915857958

##### **Phone**

+98 35 3822 4000

##### **Email**

nadia.slt75@gmail.com

##### **Web page address**

<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

##### **City**

tehran

##### **Province**

Tehran

##### **Postal code**

19569-44413

##### **Phone**

+98 21 2712 2000

##### **Email**

pourdowlat\_g@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Masoud Mirzaei

##### **Street address**

Bahonar Square, the central building of Yazd University of Medical Sciences

##### **City**

Yazd  
**Province**  
Yazd  
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9856783459  
**Phone**  
+98 35 3146 2056  
**Email**  
mmirzaei@ssu.ac.ir  
**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  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Unit 701,Floor7,Negar complex, Negaran alley,  
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nadia.slt75@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**

Dr.Fateme Saghafi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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saghafi.fa@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Nadia Soltani Gerdefaramarzi  
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University student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
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**Phone**  
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**Email**  
nadia.slt75@gmail.com

## 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