# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The role of colchicine in the treatment of covid-19 patients hospitalized in the intensive care unit

## Protocol summary

**Study aim**
The role of colchicine in the treatment of patients with Covid-19 Hospitalized in the intensive care unit

**Design**
Randomized clinical trial with parallel groups on 80 patients. Randomization will be performed using even and odd numbers.

**Settings and conduct**
The present study will be performed on 80 patients with Covid 19 admitted to the pulmonary intensive care unit of Imam Reza Hospital in Tabriz. Blinding will not be done. Patients will be examined in two groups of intervention (colchicine with routine treatment) and control (routine treatment).

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Covid-19 diagnosis based on PCR or clinical signs with lung CT scan, consent to participate in the study, hospitalization in the ICU. Exclusion criteria: Pregnancy or lactation, liver failure, patient dissatisfaction, colchicine sensitivity, renal glomerular clearance less than 20.

**Intervention groups**
Intervention group: Patients will receive methylprednisolone, Ramedsivir, cefepime, vitamin C, vitamin D, vitamin E, diphenhydramine and pantoprazole, the dose of which according to the ICU physician with colchicine tablets that 1 mg loading dose and 0.5 mg in every morning and night for ten days. Control group: Patients will receive methylprednisolone, ramsadivir, cefepime, vitamin C, vitamin D, vitamin E, diphenhydramine and pantoprazole, the dose of which, according to the ICU physician, for ten days.

**Main outcome variables**
Disease severity by APACHE II Score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210913052467N1**
Registration date: **2022-04-29, 1401/02/09**
Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**
Update count: **0**

**Registration date**
2022-04-29, 1401/02/09

**Registrant information**

**Name**
Omid Reshadi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 44 3625 8506

**Email address**
dr.omidre@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-05-22, 1401/03/01

**Expected recruitment end date**
2022-08-22, 1401/05/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The role of colchicine in the treatment of covid-19 patients hospitalized in the intensive care unit

**Public title**

The role of colchicine in the treatment of covid-19 patients

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Proved Covid-19 diagnosis based on positive PCR test or clinical evidence and CT scan of the lung Hospitalized in the intensive care unit Satisfaction for the study

**Exclusion criteria:**
Pregnancy or breastfeeding Liver failure Patient dissatisfaction Sensitivity to colchicine Renal glomerular clearance less than 20

**Age**
From **18 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, a simple computer-aided randomization method will be used. A list of numbers from 1 to 80 will be prepared in this method. This list is randomly divided into numbers. Depending on the time of hospitalization, one of these numbers will be assigned to the patient and based on the list created and the order of pairs and individuals, patients will be assigned to the intervention and control groups. The intervention group will be even numbers, and the control group will be odd numbers.

**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 Vice chancellor for research, Tabriz University of Medical Sciences

**Street address**
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5166614766

**Approval date**
2021-06-21, 1400/03/31

**Ethics committee reference number**
IR.TBZMED.REC.1400.262

## Health conditions studied

### 1

**Description of health condition studied**
Covid-19

**ICD-10 code**
J12.81

**ICD-10 code description**
Pneumonia due to SARS-associated coronavirus

## Primary outcomes

### 1

**Description**
Disease severity

**Timepoint**
At the beginning of the study and 10 days after the intervention

**Method of measurement**
APACHE Score II

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Patients will recieve methylprednisolone, ramsadivir, cefipime, vitamin C, vitamin D, vitamin E, diphenhydramine and pantoprazole; the dose of which according to the ICU specialist with 1 mg loading and 0.5 mg of colchicine and 0.5 mg every morning and night for 10 days.

**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients will recieve methylprednisolone, ramsadivir, cefipime, vitamin C, vitamin D, vitamin E, diphenhydramine and pantoprazole; the dose of which according to the ICU specialist for 10 days.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Emam Reza Hospital
**Full name of responsible person**
Dr. Kamran Shadvar
**Street address**
Golghasht Street, Daneshgah Street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614756
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+98 41 3334 7054
**Email**
imamrezahospital@tbzmed.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Samiee
**Street address**
Third Floor, Number 2 central building, Golgasht street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5138665793
**Phone**
+98 41 3335 7310
**Email**
samiei.moh@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tabriz 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**
Tabriz University of Medical Sciences
**Full name of responsible person**
Omid Reshadi
**Position**
Medical inetrn
**Latest degree**
Medical doctor
**Other areas of specialty/work**
General Practitioner
**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Tabriz University of Medical Sciences

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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**
No - There is not 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**
Study data is categorized and coded with no identifiable names.
**When the data will become available and for how long**
Access to study data after publication of the result is available in the journal.
**To whom data/document is available**
Anyone interested in using the data can access the study data.
**Under which criteria data/document could be used**
Study data can be used for comparison with other results.
**From where data/document is obtainable**
Refer to the study's scientific or public accountability person for data.
**What processes are involved for a request to access data/document**
The request will be sent by email to person responsible for scientific or public inquiries.
**Comments**