

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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 Sciences, 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 receive 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 receive 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

Phone

+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, Golghasht 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

No.1, Mollsadra blvd, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5155891864

Phone

+98 44 3625 8506

Fax

+98 44 3625 8506

Email

Dr.omidre@gmail.com

Person responsible for scientific 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

No.1, Mollsadra blvd, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5155891864

Phone

+98 44 3625 8506

Fax

+98 44 3625 8506

Email

Dr.omidre@gmail.com

Person responsible for updating data

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

No.1, Mollsadra blvd, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5155891864

Phone

+98 44 3625 8506

Fax

+98 44 3625 8506

Email

Dr.omidre@gmail.com

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