

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of colchicine in the treatment of patients with COVID-19

Protocol summary

Study aim

Evaluation of the effect of colchicine in the treatment of patients with COVID-19

Design

This study is a double-blind clinical trial with parallel groups. In this study, 82 patients with COVID-19 who met the inclusion criteria were divided into two identical groups, colchicine and placebo, using a simple individual randomization method. This is a phase 3 trial.

Settings and conduct

In this double-blind clinical trial study, 82 patients with COVID-19 who met the inclusion criteria were included in the study. These patients are divided into two equal groups of colchicine and placebo by individual randomization method. In the colchicine group, in addition to the standard treatment, patients receive one 500 microgram of colchicine tablets daily for 10 days. In the placebo group, patients receive a placebo tablet containing starch in addition to standard treatment. Finally, the two groups are compared in terms of main outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with COVID-19 infection 16 years and older , Patients admitted to the infectious ward of COVID-19 hospitals in Arak Non-entry criteria : Pregnancy and lactation , Existence of liver and kidney disorders , Age less than 16 years

Intervention groups

In the colchicine group, in addition to the standard treatment, patients receive one 500 microgram of colchicine tablets daily for 10 days. In the placebo group, patients receive a placebo tablet containing starch in addition to standard treatment.

Main outcome variables

Duration of hospitalization, complete blood cell count, liver function test, serum urea and creatinine, creatine phosphokinase, serum sodium and potassium levels, blood sugar, serum magnesium level, serum lactate dehydrogenase level, ferritin, oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N7**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of colchicine in the treatment of patients with COVID-19

Public title

Evaluation of the effect of colchicine in the treatment of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 infection 16 years and older
Patients admitted to the infectious ward of COVID-19 hospitals in Arak

Exclusion criteria:

Pregnancy and lactation Existence of liver and kidney disorders Age less than 16 years

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simply an individual with an envelope. In this method, we will select a number of cards or letters as the intervention group and the same number of cards for the control group, then we will merge the cards together and take out one card and The allocation was recorded and the card will be returned to all other cards after it is removed, then the cards will be merged again and another card will be issued. This process will continue until a random sequence is reached according to the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in one group, in addition to the standard treatment, colchicine tablets are given. In the other group, a processed placebo tablet containing starch is used instead of calcicin. Therefore, the participant and the caregiver (nurse) are unaware of the contents of the pill and the study group. The pills are delivered to the nurse by the prepared researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.ARAKMU.REC.1400.042

Health conditions studied

1

Description of health condition studied

Coronavirus disease 2019

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

After patient discharge

Method of measurement

Days of hospitalization

2

Description

oxygen saturation

Timepoint

The first, third, fifth and seventh day of hospitalization

Method of measurement

Oximeter pulse

3

Description

Laboratory findings (complete blood cell count, liver function test, serum urea and creatinine, creatine phosphokinase, serum sodium and potassium levels, blood sugar, serum magnesium level, serum lactate dehydrogenase level, ferritin)

Timepoint

The first and seventh day of hospitalization

Method of measurement

Taking a blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to the standard treatment, patients receive one 500 microgram of colchicine tablets daily for 10 days.

Category

Treatment - Drugs

2

Description

Control group: patients receive a placebo tablet containing starch in addition to standard treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr hospital

Full name of responsible person

Dr Hosein Sarmadian

Street address

Valiasr Hospital, Shahid Shiroudi Street, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Research Assistant, Arak University of Medical

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hosein Sarmadian

Position

Arak

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Ehsanollah Ghznavi Rad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Nazanin Pourafshari

Position

Infectious disease Resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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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

Yes - There is 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

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2022/4/20 to 2026/4/20 for 4 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

University researchers

From where data/document is obtainable

Dr Hosein Sarmadian

What processes are involved for a request to access data/document

Letter writing should be done with professors and universities.

Comments