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 seyyed 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

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

hosseinsarmadian2015@yahoo.com

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 Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

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

Street address

Valiasr Hospital,Shahid Shiroudi Street, Arak, Iran

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

hosseinsarmadian2015@yahoo.com

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

Street address
Valiasr Hospital,Shahid Shiroudi Street, Arak, Iran

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Fax
+98 86 3222 2003

Email
e.ghaznavirad@arakmu.ac.ir

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

Street address
Valiasr Hospital,Shahid Shiroudi Street, Arak, Iran

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Fax
+98 86 3222 2003

Email
nazanin.pourafshari21@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
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