Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19

Protocol summary

Study aim

1. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the outcome including mortality, transference to ICU and discharge 2. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the hospitalization duration 3. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the cessation of fever

Design

clinical trial, blinded, phase III, with control group, 100 patients divided into 2 groups, randomized using random number table.

Settings and conduct

This blinded clinical trial will be done in Imam Reza hospital of Ardabil on 100 COVID19 patients divided into 2 groups. the participants will be blinded to their regimen.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Pulmonary involvement seen in CT-Scan compatible with COVID19 2. Positive PCR of COVID19 Exclusion criteria: 1. Sensitivity to any medications of regimen 2. Renal failure 3.Heart diseas 4. Pregnancy 5. Reluctance to participate in the study

Intervention groups

Individuals of intervention group will receive 1 mg tablet of colchicine daily. The participants of the placebo group will receive a similar tablet without therapeutic effects.

Main outcome variables

Hospitalization duration; cessation of fever; outcome including mortality; transference to ICU and discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047126N1**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**
Update count: **0**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Farzad Salehzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19

Public title

Evaluation of colchicine in treatment of coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive PCR for COVID19

Exclusion criteria:

Sensitivity of patients to any medication that is in the regimen Renal failure Heart disease Pregnancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be divided into intervention or placebo group based on random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study the participants (patients) will be kept blind to the regimen

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah street

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Province

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Postal code

5618953141

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.ARUMS.REC.1399.050

Health conditions studied

1

Description of health condition studied

Pulmonary infection of COVD19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Hospitalization outcome

Timepoint

Last day of hospitalization in the section

Method of measurement

Calendar

2

Description

Fever cessation

Timepoint

Before hospitalization and 1, 3, 5, 7 days after hospitalization

Method of measurement

calendar

3

Description

Hospitalization time

Timepoint

First and last day of hospitalization

Method of measurement

Calendar

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 1 mg tablet of colchicine daily for 10 days

Category

Treatment - Drugs

2

Description

Control group: A placebo tablet daily for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza (pbuh) of Ardabil

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
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Position
professor

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Person responsible for updating data

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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