

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Efficacy and safety of colchicine on clinical improvement in patients with COVID-19: A randomized, double blind clinical trial

Protocol summary

Study aim

Colchicine efficacy and safety on clinical symptoms improvement in patients with COVID-19

Design

Two arm parallel group randomized, double blind clinical trial on 110 patients. Permuted block will be used for randomization.

Settings and conduct

Adult patients(over 18 years) with COVID-19 diagnosis according inclusion criteria and have been admitted to to Ibn Sina Hospital, randomly assigned to colchicine or placebo. Both groups will receive therapeutic regimen including subcutaneous injection of 250 microgram interferon beta 1b every other day and remdesivir 200 mg for first day then 100 mg daily for 5 days, Physician, patients and assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria or PCR
Exclusion criteria: The presence of any underlying disease that increases the likelihood of side effects from colchicine

Intervention groups

The recruited patients will be candidate to receive colchicine of Modava pharmaceutical company or placebo for one week according to randomization table. Colchicine will be administered 2 milligrams as loading dose and then one milligram daily for seven days and in control group placebo tablets with same size and color will be administered. Placebo will produce in pharmacy faculty.

Main outcome variables

Determination of colchicine effects on clinical improvement of COVID-19 symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044429N5**

Registration date: **2021-02-18, 1399/11/30**

Registration timing: **prospective**

Last update: **2021-02-18, 1399/11/30**

Update count: **0**

Registration date

2021-02-18, 1399/11/30

Registrant information

Name

Monireh Ghazaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-22, 1399/12/04

Expected recruitment end date

2021-03-24, 1400/01/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of colchicine on clinical improvement in patients with COVID-19: A randomized, double blind clinical trial

Public title

Colchicine effects on treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria (presence of any symptoms of cough, shortness of breath, fever, and CT scan of the lung for evidence of involvement consistent with COVID-19 infection) or PCR and Had clinical symptoms of COVID-19 within two weeks

Exclusion criteria:

Pregnancy and lactation Severe hepatic insufficiency (Child-pugh C) Renal insufficiency (GFR less than 30 ml/min) Allergy history of colchicine Thrombocytopenia (Platelets less than 100,000 /mm³) Not consent

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using the block method by a person who is not related to the study. Packages containing the drug and placebo are completely similar in shape and color. Randomization of serial numbers of drug packages and placebo by a person who is not involved in the project according to randomized table. The number of the bottle corresponded with the number of the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Outcome evaluator and participant are blinded (double blind) and aware from grouping (intervention or placebo). The medicinal substance and placebo are completely similar in shape and color

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Ibn Sina Hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

4816864193

Approval date

2021-02-16, 1399/11/28

Ethics committee reference number

IR.MAZUMS.REC.1399.914

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

respiratory rate

Timepoint

Before intervention and daily during the study

Method of measurement

physical exam

2

Description

blood oxygen saturation

Timepoint

Before intervention and daily during the study

Method of measurement

pulse oximeter

3

Description

fever recovery

Timepoint

Before intervention and daily during the study

Method of measurement

thermometer

4

Description

therapeutic regimen safety

Timepoint

Daily during the study
Method of measurement
Incidence of any side effects

5

Description

CRP

Timepoint

before intervention and then three times weekly during the study

Method of measurement

CRP laboratory kite

6

Description

lymphocyte count

Timepoint

before intervention and then daily during the study

Method of measurement

Cell blood count test

Secondary outcomes

1

Description

Hospital stay duration

Timepoint

End of treatment

Method of measurement

Patient file

2

Description

Mortality rate

Timepoint

Daily during the study

Method of measurement

patient file

Intervention groups

1

Description

Intervention group: Medication regimen including 250 mcg interferon beta 1 b subcutaneous injection every other day for at least 3 doses plus remdesivir 200 mg as first dose then 100 mg daily for 5 days with Colchicine tablet of Mofid company at dose of 2mg as loading dose then 1 mg daily for 7 days

Category

Treatment - Drugs

2

Description

Control group: Patients with inclusion criteria who received therapeutic regimen of 250 mcg interferon beta

1 b as every other day subcutaneous injection for at least 3 doses and remdesivir 200 mg as first dose then 100 mg daily for 5 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Monireh Ghazaeian

Street address

Ibn Sina hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

4816864193

Phone

+98 11 3334 3011

Email

ghazaeianm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way

City

Sari

Province

Mazandaran

Postal code

4816864193

Phone

+98 11 3448 4800

Email

majsaeedi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
نخدهقئا لاشطششهشء
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Clinical pharmacy
Street address
Ibn Sina hospital, Pasdaran Blvd, Sari
City
Sari
Province
Mazandaran
Postal code
4816864193
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Monireh Ghazaeian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Clinical pharmacy
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4816864193
Phone
+98 11 3334 3010
Email
ghazaeianm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Monireh Ghazaeian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Clinical pharmacy
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
48157-33971
Phone
+98 11 3334 3010
Email
ghazaeianm@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

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

IPD collected for the primary outcome measures are to be shared.

When the data will become available and for how long

The data will be available one year after publication

To whom data/document is available

Academic researchers, medical team and scientific institutes

Under which criteria data/document could be used

Requests for sharing data should be sent to the person responsible for general inquiries.

From where data/document is obtainable

Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences.

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

Person in charge of scientific study will reply to the request within 10 days. ghazaeianm@gmail.com

Comments