Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 8863 6864

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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 elevator 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

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Ibn Sina hospital, Pasdaran Blvd

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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

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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

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

ئخدهقثا لاشطشتهشد

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Clinical pharmacy

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Ibn Sina hospital, Pasdaran Blvd, Sari

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Person responsible for updating data

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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

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