

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of colchicine tablet efficacy as an adjuvant treatment for patients with mild to moderate COVID-19 in Qaem Hospital, Mashhad: A triple-blind randomized placebo controlled clinical trial

Protocol summary

Study aim

Evaluation of the colchicine efficacy as a supplement for treatment of mild to moderate COVID-19

Design

This is a randomized triple-blind, parallel group clinical trial on 40 patients with mild to moderate covid-19 (20 patients in treatment group and 20 patients in placebo group).

Settings and conduct

This study will perform on 40 patients with clinical or laboratory diagnosis of mild to moderate covid-19 who refer to Qaem Hospital, Mashhad, Iran. They whether will received one colchicine 1mg tablet daily for 2 weeks in treatment group or one placebo tablet in placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Laboratory or radiologic or clinical diagnosis of mild to moderate COVID-19, age between 18-85y, sign of the written consent Exclusion criteria: pregnancy or lactation, history of allergy to colchicine, concomitant use of protease inhibitors, potent CYP3A4 or ppg inhibitors or inducers, adverse drug reaction occurrence, past medical diseases (e.g. kidney, hepatic, heart failure, active GI ulcer, neuromuscular disease, chronic diarrhea, malabsorption)

Intervention groups

Treatment group: one colchicine tablet daily for 2 weeks, Control group: one placebo tablet daily for two weeks

Main outcome variables

Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients' clinical outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N2**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **prospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of colchicine tablet efficacy as an adjuvant treatment for patients with mild to moderate COVID-19

in Qaem Hospital, Mashhad: A triple-blind randomized placebo controlled clinical trial

Public title

Evaluation of the colchicine tablet efficacy as an adjuvant therapy for patients with mild to moderate COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical or laboratory diagnosis of mild to moderate covid-19 age between 18-85 y sign of written consent

Exclusion criteria:

use of protease inhibitors like kaletra history of allergy to colchicine pregnancy and lactation hepatic failure (child pugh C), kidney failure (GFR<30 ml/min), or heart failure with EF<40% concomitant use of CYP3A4 or pgg potent inhibitors or inducers concomitant use of statins except rosuvastatin active GI disturbances like active peptic ulcers transmission of patients to ICU ward or his/her intubation patients on colchicine for behcet disease or Mediterranean fever or gout patients with history of neuromuscular disease or chronic diarrhea or malabsorption

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

With the help of a randomization list provided by randomization.com site, patients will receive code 1 or 2 and will be included in placebo or medication group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The colchicine and placebo tablets will be packaged in identical-looking bottle and delivered to the clinician. Patients who meet the inclusion criteria are selected by clinician to be included in the study, randomly assigned to a drug or placebo group and given a bottle with A or B mark. Patients will be evaluated in the course of treatment by the physician and the pharmacy student. Data collection and analysis are performed by the pharmacy student and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qureshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.MUMS.REC.1399.096

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

fever

Timepoint

daily

Method of measurement

thermometer

2

Description

clinical response to treatment (including improvement of cough, myalgia, headache, Olfactory and taste disorders)

Timepoint

daily

Method of measurement

Based on patients examination and interview

3

Description

radiologic response

Timepoint

two weeks after treatment

Method of measurement

lung CT scan

4

Description

laboratory response

Timepoint

weekly

Method of measurement

assessment of serum level of CRP and CBC diff

5

Description

drug adverse reaction

Timepoint

daily

Method of measurement

patient file and interview

Secondary outcomes

1

Description

duration of hospitalization

Timepoint

end of the treatment

Method of measurement

patients' file

2

Description

patients' clinical outcome

Timepoint

at the of the treatment

Method of measurement

patients' file

Intervention groups

1

Description

Intervention group: one colchicine 1mg tablet daily for two weeks

Category

Treatment - Drugs

2

Description

Control group: placebo with same appearance of colchicine tablet one daily for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Quem hospital

Full name of responsible person

Sepideh Elyasi

Street address

Quem Hospital, Ahmadabad Ave., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3180 1588

Email

elyasis@mums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1337

Email

tafaghodim@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

elyasis@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Ferdosi University, Vakilabad Aven.

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

elyasis@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

elyasis@mums.ac.ir

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.

When the data will become available and for how long

One year after the end of the study it will be published and available in databases.

To whom data/document is available

If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific centers.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

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

After receiving the query, dependent on the requested data, the scientific responsible person of the study will

response to the query in coordinate with the sponsor

within 2 weeks

Comments