Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 Quem 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 pgp 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 pgp 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