Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the effectiveness of Colchicine tablets in mortality and duration of ICU hospitalization in patients under mechanical ventilation diagnosed with COVID-19

Protocol summary

Study aim

Determining the effect of Colchicine on the recovery of patients with COVID-19 in the intensive care unit
Determining the effect of Colchicine on the death of patients with COVID-19Determining the effectiveness of Colchicine tablets in mortality and duration of ICU hospitalization in mechanically ventilated patients of COVID-19

Design

Clinical trial with a control group, having parallel groups, double-blind, randomized, phase 2 on 60 patients. Randomization of blocks with 4 blocks is done for randomization.

Settings and conduct

The location of this study is in Amir Al-Momenin Hospital located in Qom, by randomly selecting patients COVID-19 to be placed in the intervention and control groups, double- blinded including data recorder and data analyzer.

Participants/Inclusion and exclusion criteria

Entry criteria : Patients of COVID-19 (positive by PCR test), intubated and connected to a ventilator, age between 30 and 60.Criterion of patient non-entry: If the patient has liver enzymes above 200 or intubated less than 24 hours after admission, he or she will be excluded from the study.

Intervention groups

Intervention group; Routine treatment of patients according to the protocols, plus 2 mg of Colchicine daily control group; Routine treatment of patients according to the protocols

Main outcome variables

Patients mortality rate; The number of days of their hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211017052786N1**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **prospective**

Last update: **2022-01-18, 1400/10/28**
Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

Amir Hossein Moradi Rafigh

Name of organization / entity

Qom university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 25 3885 6440

Email address

amirmmr287@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-05-19, 1401/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of Colchicine tablets in mortality and duration of ICU hospitalization in patients under mechanical ventilation diagnosed with COVID-19

Public title
Efficacy of Colchicine in the treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People who are definitely hospitalized for Covid-19 diagnosis and are under mechanical ventilation Minimum age age of 30

Exclusion criteria:
Patients over age of 60 The patients who are pregnant or have an infant child Patients with liver enzyme problems Patients who are intubated in less than 24 hours

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization using 4 blocks, randomization criterion is performed using block random allocation with 4 blocks, in which all four possibilities A, A, B, B and A, B, B, B and A, B, A, B and B, A, B, A are written on four cards and four patients randomly get picked up in each groups . The ward manager takes the patients card out of the bag and the patients are divided into groups . For example, if the card is A, A, B, B the first and second patients are in the first group, and the third and fourth patients are in the second group, and also for the next four patients, a card is picked again.

Blinding (investigator's opinion)
Double blinded

Blinding description
The person filling the questionnaire will not be aware of the type and method of treatment of the patient. The treating physician will not be involved in the data entry or analysis process.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of QOM University of Medical Sciences

Street address
No.10, 13th Ave., Emam Street.

City
Qom

Province
Ghoum

Postal code
3718913997

Approval date
2021-12-30, 1400/10/09

Ethics committee reference number
IR.MUQ.REC.1400.026

Health conditions studied

1

Description of health condition studied
Covid 19

ICD-10 code
U07.2

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
CRP level of the patient's blood

Timepoint
The first and fifth day of study

Method of measurement
Patient blood test

2

Description
Patient's blood lymphocyte count

Timepoint
The first and fifth days of study

Method of measurement
Patient blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Colchicine (N-[(7S)-1,2,3,10-Tetramethoxy-9-oxo-5,6,7,9-tetrahydrobenzo[a]heptalen-7-yl]acetamide) produced by (Seid SA) company is administered orally to patients for 5 days according to the anesthesia doctor's instructions and according to the treatment protocol.
Category
Treatment - Drugs

2

Description
Control group: A group that is routinely treated with drugs such as Corticosteroids and Remdesivir according to Covid 19 protocols.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Vahid Damanpak Moghadam
Street address
Shahid Beheshti Blvd
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Email
Bmc@muq.ac.ir
Web page address
https://bmc.muq.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Vahid Damanpak Moghadam
Street address
No. 83, Forth Ave., Safa Shahr Street
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3285 2720
Email
Amirmmr287@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Amir Hossein Moradi Rafigh
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Anesthesiology
Street address
No. 46, 32th Ave., Keshavarz Shomali Blvd.
City
Qom
Province
Ghoum
Postal code
3715178817
Phone
+98 25 3885 6440
Email
Amirmmr287@gamil.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Amir Hossein Moradi Rafigh
Position
Student
Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

No. 46, 32th Ave., Keshavarz Shomali Blvd.,

City

Qom

Province

Ghoum

Postal code

3715178817

Phone

+98 25 3885 6440

Email

Amirmmr287@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Amir Hossein Moradi Rafigh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

No. 46, 32th Ave., Keshavarz Shomali Blvd.,

City

Qom

Province

Ghoum

Postal code

3715178817

Phone

+98 25 3885 6440

Email

Amirmmr287@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to the present study

Study Protocol

No - There is not 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

No - There is not 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