

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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-19  
Determining 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

Ghous

##### 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

Ghous University of Medical Sciences

##### Full name of responsible person

Vahid Damanpak Moghadam

##### Street address

No. 83, Forth Ave., Safa Shahr Street

##### City

Qom

##### Province

Ghous

##### 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

Ghous 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

Ghous 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.

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##### Province

Ghous

##### Postal code

3715178817

##### Phone

+98 25 3885 6440

##### Email

Amirmmr287@gamil.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ghous 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**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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Amir Hossein Moradi Rafigh

**Position**

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**Latest degree**

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**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