

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation of the Efficacy and Safety of Colchicine plus Methylprednisolone Pulse Therapy in Treatment of Covid-19 Patients with ARDS

#### Protocol summary

##### Study aim

Evaluation of the efficacy and safety of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with ARDS

##### Design

A clinical trial with control group, double blinded, randomized with random numbers table, phase2 with 80 patients.

##### Settings and conduct

A clinical trial on 80 patients with progressive covid19 disease admitted in Imam Reza Hospital ICU. Study is randomized and double blinded (both patients and assessor kept blind). in intervention group Methylprednisolone pulse therapy and Colchicine is used in addition to standard treatment in control group.

##### Participants/Inclusion and exclusion criteria

Covid-19 ICU-admitted patients with moderate to severe ARDS

##### Intervention groups

Control group: Receiving standard treatment for patients who have ARDS due to covid19 disease including Dexamethasone (8mg daily till 10 days), Interferon beta1(250 microgram till 7 days) and Remdesivir (initial dose: 200mg then 100mg daily) Intervention group: in addition to receiving standard treatment for patients who have ARDS due to covid19 disease, this group will receive Methylprednisolone pulse therapy (500mg each 12h until 3 days) and Colchicine pill (2mg stat then 1mg daily)

##### Main outcome variables

Evaluation of the efficacy of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with Respiratory distress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201229049872N1**

Registration date: **2021-04-22, 1400/02/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-22, 1400/02/02**

Update count: **0**

##### Registration date

2021-04-22, 1400/02/02

##### Registrant information

##### Name

Mostafa Nematizad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4427 9498

##### Email address

mostafanemati73@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Efficacy and Safety of Colchicine plus

Methylprednisolone Pulse Therapy in Treatment of Covid-19 Patients with ARDS

## Public title

Efficacy of Colchicine in Treatment of Covid-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with COVID-19 with moderate to severe respiratory failure admitted to ICU wards

### Exclusion criteria:

Uncontrolled Diabetes Mellitus Active bacterial or viral (viral Hepatitis and HIV) or fungal infection Positive more than 0.5 Procalcitonin or positive bacterial and fungal culture of any specimen of body Sever Electrolyte disturbance History of severe reaction to Steroidal products Active Gastrointestinal bleeding

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method used in this study is the use of a table of random numbers

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants in this study, as well as outcome assessors, were kept blind

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of AJA University of Medical Sciences

##### Street address

AJA University of Medical Sciences, Shahid Etemadzade Ave, West Fatemi Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### Approval date

2021-04-20, 1400/01/31

##### Ethics committee reference number

IR.AJAUMS.REC.1400.011

## Health conditions studied

### 1

#### Description of health condition studied

Covid 19

#### ICD-10 code

B97.2

#### ICD-10 code description

Coronavirus as the cause of diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Evaluation of the efficacy of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with Respiratory distress

#### Timepoint

During the hospitalization period

#### Method of measurement

According to measurement of secondary outcome variables

## Secondary outcomes

### 1

#### Description

Duration of hospitalization in ICU

#### Timepoint

During the hospitalization period

#### Method of measurement

According to ICU hospitalization and discharge time

### 2

#### Description

Duration of being intubated

#### Timepoint

During the hospitalization period

#### Method of measurement

Period between intubation and extubation time

### 3

#### Description

Duration of staying in hospital

#### Timepoint

During the hospitalization period

#### Method of measurement

The difference between the time of admission and the time of discharge

#### 4

##### Description

Patient's death

##### Timepoint

During the hospitalization period

##### Method of measurement

Based on patient file information

#### 5

##### Description

SOFA score

##### Timepoint

During the hospitalization period

##### Method of measurement

Calculation based on defined table

### Intervention groups

#### 1

##### Description

Control group: Receiving standard treatment for patients who have ARDS due to covid19 disease including Dexamethasone (8mg daily till 10 days), Interferon beta1(250 microgram till 7 days) and Remdesivir (initial dose: 200mg then 100mg daily)

##### Category

Treatment - Drugs

#### 2

##### Description

Intervention group: in addition to receiving standard treatment for patients who have ARDS due to covid19 disease, this group will receive Methylprednisolone pulse therapy (500mg each 12h until 3 days) and Colchicine pill (2mg stat then 1mg daily)

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Imam Reza Hospital

###### Full name of responsible person

Ebrahim Hazrati

###### Street address

Imam Reza hospital - Etemadzadeh Ave - West Fatemi Street

###### City

Tehran

###### Province

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##### Postal code

1411718539

##### Phone

+98 21 8609 6350

##### Email

info@ajaums.ac.i

##### Web page address

https://imamreza.ajaums.ac.ir/

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Artesh University of Medical Sciences

###### Full name of responsible person

Ebrahim Hazrati

###### Street address

AJA University of Medical Sciences, Shahid Etemadzade Ave, West Fatemi Ave

###### City

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###### Postal code

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###### Phone

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###### Fax

+98 21 8833 7919

###### Email

info@ajaums.ac.ir

###### Web page address

https://www.ajaums.ac.ir/

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Artesh 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

Artesh University of Medical Sciences

###### Full name of responsible person

Ebrahim Hazrati

###### Position

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Email**

dr.hazrati.e@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Reza Mosaed

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmacotherapy

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reza-mosaed@ajaums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Mostafa Nematizad

**Position**

Non-faculty general physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Email**

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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**

It's no more information

**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