

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Study aim

Evaluation of the efficacy of methylprednisolone pulse therapy in patients with respiratory distress

##### Design

This study is a two arm parallel group, randomized clinical trial in phase 2 which will be carried out on 40 hospitalized COVID-19 patients. Patients randomly divided into two groups.

##### Settings and conduct

This clinical trial will be carried out on 40 hospitalized COVID-19 patients in Intensive care unit of Imam Reza hospital of AJA university of medical sciences, Iran. Patients will be received 1000mg methylprednisolone pulse for 3 days.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients admitted to ICU with moderate to severe Covid-19 infection needs respiratory support PaO<sub>2</sub>/FiO<sub>2</sub> less than 300 Progression of disease severity and not responding to standard treatment Prediction of intubation need in next 24 hours Exclusion Criteria: Uncontrolled diabetes mellitus Active bacterial, fungal infection Procalcitonin more than 0.5 History of hypersensitivity to corticosteroids Active GI bleeding

##### Intervention groups

Control group: receive standard regimen for COVID-19  
Corticosteroid group: receive standard regimen for COVID-19 plus Methylprednisolone (1000mg for 3 days).

##### Main outcome variables

Changes in respiratory distress Changes in O<sub>2</sub> Saturation Extubation Discharge from ICU Mortality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200406046963N1**

Registration date: **2020-04-22, 1399/02/03**

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

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

##### Registration date

2020-04-22, 1399/02/03

##### Registrant information

###### Name

Reza Mosaed

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8609 6001

###### Email address

reza.mosaed@ajajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-30, 1399/01/11

##### Expected recruitment end date

2020-05-18, 1399/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

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

##### Public title

Evaluation of the efficacy and safety of methylprednisolone pulse therapy in treatment of Covid-19 patients with Acute respiratory distress syndrome

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Patient with moderate to severe Covid-19 admitted to ICU PaO<sub>2</sub>/FiO<sub>2</sub> Less than 300 Progression of disease severity and not responding to standard treatment prediction of intubation for next 24 hours

### **Exclusion criteria:**

Uncontrolled diabetes mellitus Active GI bleeding history of corticosteroid hypersensitivity sever electrolyte imbalances Procalcitonin more than 0.5 active bacterial, viral ( HIV, Hepatitis) and fungal infection

## **Age**

From **18 years** old to **90 years** old

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **40**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Simple randomization with random allocation software and allocate patients to two groups of investigation (A) and control (B)

## **Blinding (investigator's opinion)**

Not blinded

## **Blinding description**

## **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**

Etemadzadeh Ave, west Fatemi street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411718541

#### **Approval date**

2020-04-04, 1399/01/16

#### **Ethics committee reference number**

IR.AJAUMS.REC.1399.008

## **Health conditions studied**

### 1

#### **Description of health condition studied**

COVID-19 Disease

#### **ICD-10 code**

U07.2,

#### **ICD-10 code description**

COVID-19

## **Primary outcomes**

### 1

#### **Description**

Mortality rate

#### **Timepoint**

from including to study to 60 days

#### **Method of measurement**

observation

### 2

#### **Description**

blood O<sub>2</sub> saturation

#### **Timepoint**

before and during the study for 14 days

#### **Method of measurement**

pulse Oximeter

### 3

#### **Description**

oxygen therapy need

#### **Timepoint**

before and during the study for 14 days

#### **Method of measurement**

Clinical

## **Secondary outcomes**

### 1

#### **Description**

Chest CT Scan changes 48 hours after starting pulse therapy

#### **Timepoint**

48 hours after starting methylprednisolon pulse therapy

#### **Method of measurement**

Chest CT Scan

### 2

#### **Description**

ICU length of stay

#### **Timepoint**

During the study until ICU discharge

#### **Method of measurement**

Patients file

### 3

#### Description

Sequential Organ Failure Assessment (SOFA) Score changes

#### Timepoint

before and during the study

#### Method of measurement

clinical

## Intervention groups

### 1

#### Description

Intervention group: Patients hospitalized with COVID-19 disease who in addition to their standard treatment ( Hydroxychloroquine 400mg daily) will be received 1000mg/day Methylprednisolone for 3 days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients hospitalized with COVID-19 disease who are received standard treatment ( Hydroxychloroquine 400mg daily)

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Ebrahim Hazrati

##### Street address

Etemadzadeh Ave, west Fatemi st

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1411718541

##### Phone

+98 21 8609 5072

##### Email

dr.hazart.e@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Ramin Hamidi Farahani

#### Street address

Etemadzadeh ave, west Fatemi st

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#### Phone

+98 21 8609 6350

#### Email

Rgsramin@yahoo.com

#### 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

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

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Assistant professor  
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## Person responsible for updating data

### Contact

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Artesh University of Medical Sciences  
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Reza Mosaed  
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reza.mosaed@ajaums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

not shared

### When the data will become available and for how long

After acceptance of a journal

### To whom data/document is available

All medical professionals and scientists

### Under which criteria data/document could be used

There is no restriction on access to information

### From where data/document is obtainable

Dr.Ebrahim Hazrati, AJA University of Medical sciences

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

Refer to the project supervisor

### Comments