

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411718541

##### **Phone**

+98 21 8609 5072

##### **Email**

dr.hazrart.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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1411718541

#### **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

##### **Street address**

Etemadzadeh Ave, west Fatemi st

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

14117118541

##### **Phone**

+98 21 8609 6350

##### **Email**

dr.hazrart.e@gmail.com

## **Person responsible for scientific 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  
**Street address**  
Etemadzadeh Ave, west Fatemi st  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411718541  
**Phone**  
+98 21 8609 6350  
**Email**  
dr.hazrart.e@gmail.com

## Person responsible for updating data

### 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**  
Medical Pharmacy  
**Street address**  
Etemadzadeh Ave, west Fatemi st  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
1411718541  
**Phone**  
+98 21 8609 6001  
**Email**  
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