

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The efficacy of methylprednisolone mini pulse on the treatment of COVID-19 patients admitted to intensive care unit

#### Protocol summary

##### Study aim

Evaluating the efficacy of methylprednisolone mini pulse therapy on COVID-19 patients admitted to intensive care unit

##### Design

This study is a two arm parallel non-randomized clinical trial which will be carried out on 60 hospitalized COVID-19 patients.

##### Settings and conduct

This clinical trial will be carried out on 60 hospitalized COVID-19 patients in Intensive care unit of imam Khomeini hospital of Ardabil university of medical sciences, Iran. Intervention group will receive 250 mg 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.

Exclusion Criteria: Uncontrolled diabetes mellitus, active bleeding, Active bacterial or fungal infection, positive procalcitonin, hypersensitivity to corticosteroids, previous immunosuppressor or corticosteroid use.

##### Intervention groups

Control group will receive standard regimen for COVID-19 and intervention group will receive standard regimen for COVID-19 plus Methylprednisolone 250 mg 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: **IRCT20170716035126N4**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **retrospective**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

##### Registration date

2020-08-26, 1399/06/05

##### Registrant information

###### Name

Afshin Habibzadeh

###### Name of organization / entity

Ardabil University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3352 2391

###### Email address

a.habibzade@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-10, 1399/04/20

##### Expected recruitment end date

2020-08-10, 1399/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of methylprednisolone mini pulse on the treatment of COVID-19 patients admitted to intensive care unit

##### Public title

The efficacy of methylprednisolone mini pulse on the

treatment of COVID-19 patients admitted to intensive care unit

## 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 or those under mechanical ventilation

### Exclusion criteria:

,ncontrolled diabetes mellitus Active GI bleeding history of corticosteroid hypersensitivity sever electrolyte imbalances History of treatment with immune-suppressor agents History of corticosteroid use Positive procalcitonin active bacterial or fungal infection HIV and hepatitis

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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 Ardabil University of Medical Sciences

##### Street address

Ardabil University of Medicine Sciences, Daneshgah St.,

##### City

Ardabil

##### Province

Ardabil

##### Postal code

۵۶۱۸۹-۸۵۹۹۱

## Approval date

2020-06-24, 1399/04/04

## Ethics committee reference number

IR.ARUMS.REC.1399.206

## 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

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with COVID-19 admitted to ICU will receive 250 mg methyl prednisolone in addition to their standard treatment for three days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients with COVID-19 admitted to ICU will receive standard treatment for COVID-19

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Yousef Mohammadi Kebar

**Street address**

Imam Khomeini Hospital, Ataei Ave.,

**City**

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**Province**

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**Postal code**

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**Phone**

+98 45 3352 2083

**Email**

yousefmk506@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Entezari Asl

**Street address**

Ardabil University of Medical Science, Daneshgah St.,

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m.entezari@arums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Afshin Habibzadeh

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Khomeini hospital, Ataei Ave.,

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Ardabil

**Postal code**

5618985991

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+98 45 3352 2391

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afshin.habibzadeh@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

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Yousef Mohammadi Kebar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

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Afshin Habibzadeh

**Position**

Consultant

**Latest degree**

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## 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**

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

**Clinical Study Report**

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

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable