# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 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, PaO2/FiO2 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 immunosupressor 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 O2 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 PaO2/FiO2 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 O2 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**

Ardabil

**Province**

Ardabil

**Postal code**

۵۶۱۸۹-۸۵۹۹۱

**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.,

**City**

Ardabil

**Province**

Ardabil

**Postal code**

۵۶۱۸۹-۸۵۹۹۱

**Phone**

+98 45 3352 2083

**Email**

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.,

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5618985991

**Phone**

+98 45 3352 2391

**Email**

afshin.habibzadeh@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Yousef Mohammadi Kebar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Khomeini Hospital, Ataei ave.,

**City**

Ardabil

**Province**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences
**Full name of responsible person**
Afshin Habibzadeh
**Position**
Consultant
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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