Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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)

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+98 45 3352 2391

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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.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Person responsible for scientific inquiries

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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