

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

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 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 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.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Yousef Mohammadi Kebar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

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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