Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 methylprednisolon 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 PaO2/FiO2 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 O2 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)

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+98 21 8609 6001

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reza.mosaed@ajaums.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 PaO2/FiO2 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

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Province

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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 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

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
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Sponsors / Funding sources

1

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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
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
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Ebrahim Hazrati
Position
Assistant professor
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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
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 scientiscts

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