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 methylprednisolone 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
Last update: 2020-04-22, 1399/02/03
Update count: 0

Registration date
2020-04-22, 1399/02/03

Registrant information
Name
Reza Mosaed
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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
- History of corticosteroid hypersensitivity
- Severe 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
- Tehran

Province
- Tehran

Postal code
- 141178541

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

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
### 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 receive 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**  
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### Sponsors / Funding sources

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**Name of organization / entity**  
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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  
**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  
**Full name of responsible person**  
Ebrahim Hazrati  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**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
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 scientists

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