Clinical Trial Protocol
Iranian Registry of Clinical Trials
19 Jan 2021

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
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
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Iran (Islamic Republic of)
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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 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

Secondary design features

Secondary Ids
empty

Ethics committees

Ethics committee
Name of ethics committee
Ethics committee of AJA University of Medical Sciences

Street address
Etemadzadeh Ave, west Fatemi street

City
Tehran

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
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.
Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
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Person responsible for general inquiries

Contact
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Full name of responsible person
Ebrahim Hazrati
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Assistant professor
Latest degree
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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**