Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparision the efficacy of 2 regimen of methylprednisolone in patient with acute respiratory distress syndrome due to CVOID-19

Protocol summary

Study aim
Determining the mortality rate of patients during hospitalization in both groups of pulse methylprednisolone group and 1 mg/per kiloogram of body weight every 12 hours.

Design
The trial has two study groups in parallel, randomized, non-blind phase 3 on 74 patients and uses rand function of excel for randomization

Settings and conduct
Patients with mild to moderate acute respiratory distress syndrome who admit to corona ward of Loghman Hakim hospital will go under study with two different regimen of methylprednisolone doses.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients older than 18 Patient with severe acute respiratory injury with symptoms of novel coronavurus during 10 recent days Posotive polymerase chain reaction (PCR) test of novel coronavirus or chest CT scan that confirms coronavirus pneumonia Mild to moderate acute respiratory distress syndrome No more than 24 hours have passed since their admission. The patient should not be under invasive mechanical ventilation when entering the study. Satisfaction to participate in the study. Exclusion criteria: Dissatisfaction of the patient or the patient's legal companion. Pregnancy and lactation. Chronic hemodialysis Heart failure Severe vasoplegic shock Pulmonary edema due to other pathology like heart failure , cirrhosis , chronic kidney failure Severe hypoxemia If patient expires lower than 3 days after beginning of treatment.

Intervention groups
One group recieves 1 mg per kg of methylprednisolone every 12 hours and other one recieve 1000 mg of methyl prednisolone daily for 3 days then keep on with 1 mg per kg every 12 hours.

Main outcome variables
mortality ratio

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130917014693N13**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date
2021-11-06, 1400/08/15

Registrant information

Name
Zahra Sahraei

Name of organization / entity
Faculty of pharmacy, Shahid beheshti university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision the efficacy of 2 regimen of methylprednisolone in patient with acute respiratory distress syndrome due to CVOID-19

Public title
comparision of the two methylprednisolone regimens in patient with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than 18 years old Severe acute respiratory injury with coronavirus infection symptoms during 10 days ago who needed for hospital admission infection with COVID-19 wich confirmed with nasal RT_PCR test or CT-scan imaging Mild to moderate acute respiratory distress syndrome No more than 24 hours have passed since their admission to the study. The patient should not be under aggressive mechanical respiration when entering the study. Consent to participate in the study.

Exclusion criteria:
Dissatisfaction of the patient or the patient's legal companion Pregnancy and lactation Chronic hemodialysis Heart failure patients Severe vasoplegic shock Pulmonary edema due to other causes like heart failure , cirrhosis, chronic kidney failure Not administrating corticosteroid more than 24 hours after beginning ARDS Severe hypoxemia If the patient expires lower than 3 days after beginning of corticosteroids

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
First, by randomized numbers list, a sequence of random numbers will be selected and patients will be allocated to interventions groups with simple randomization.

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 Shahid Beheshti University of Medical Sciences

Street address
3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2021-06-29, 1400/04/08

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.081

Health conditions studied

1

Description of health condition studied
Acute respiratory distress syndrome of covid-19 pneumonia

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Mortality ratio of patients with acute respiratory distress syndrome due to covid-19

Timepoint
first of admission and time of discharge

Method of measurement
Counting

Secondary outcomes

1

Description
Determine the need for respiratory support and determine changes to this support

Timepoint
every 24 hours

Method of measurement
Ventilation modality

2

Description
Determine the exact length of hospital stay until discharge

Timepoint

every 24 hours

Method of measurement

Counting number of days

3

Description

Determine the number of patients who need to receive hemoperfusion

Timepoint

Every 24 hours

Method of measurement

Count the number of patients and the frequency of hemoperfusion

4

Description

Determine the number of patients who need to receive other immunosuppressants such as tocilizumab

Timepoint

every 24 hours

Method of measurement

Counting the number of patients and the number of doses of other drugs

Intervention groups

1

Description

Intervention group: 1000 miligrams of methylprednisolone every 24 hours for 3 days then 1 mg/kg of methylprednisolone every 12 hours for total of 10 days

Category

Treatment - Drugs

2

Description

Intervention group: methylprednisolone 1 mg/kg every 12 hours for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Zahra sahraei

Street address

Loghman Hakim hospital , Makhsous Ave. , south Kargar Ave.

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1985717443

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Sahraei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available