

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison the efficacy of 2 regimen of methylprednisolone in patient with acute respiratory distress syndrome due to COVID-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 coronavirus 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

Country

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

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

Public title

comparison 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 wick 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

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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 milligrams 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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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