

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

High dose solumedrol in patients with severe Covid-19 infection

Protocol summary

Study aim

To evaluate the efficacy of high dose solumedrol in patients with severely hypoxemic COVID-19 infection.

Design

This is a single-center, double-blinded, randomized, and controlled parallel groups study. Each group will include a total of 30 patients. Patients will be grouped in a randomized manner via a concealed method

Settings and conduct

All patients admitted in the intensive care with severe COVID-19 infection will be randomly assigned to any of the arms in a blinded manner. The ICU nurse and the patient will be blinded. The injection will be administered in 100 ml saline which will be numbered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. written informed consent 2. Subjects age > 18 years at the time of signing the Informed Consent Form. 4. individuals with severe COVID-19 symptoms according to Berlin Criteria 6. Hospitalized patients and on Mechanical Ventilation Patients requiring FIO₂ of 0.5 or more and a PEEP of 5 mmHg or more
exclusion Criteria: 1. Pregnant females 2. Patients with HIV infection., or active tuberculosis, or a history of treatment for pulmonary tuberculosis 4. Patients with a CrCl of less than 30 ml/minute, an ejection fraction of 30% or less, or advanced liver disease 7. Patients allergic to methylprednisolone

Intervention groups

Group 1: Patients will receive standard of care and 1000 mg methylprednisolone for three consecutive days after randomization Group 2: patients will receive standard of care and a placebo medicine. Standard of care: This will include oxygen therapy, ventilatory support, antiviral drugs (remdesivir), antibiotics, fluids, PPIs, and anticoagulants.

Main outcome variables

The primary outcome will be assessed based on in-hospital mortality. The secondary outcome will be assessed based on the: 1. duration of hospital stay 2. Improvement in lung mechanics, inflammatory markers,

and incidence of infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200723048178N3**

Registration date: **2021-08-13, 1400/05/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-13, 1400/05/22**

Update count: **0**

Registration date

2021-08-13, 1400/05/22

Registrant information

Name

Ahmed Farhan

Name of organization / entity

Pakistan Institute of Medical Sciences

Country

Pakistan

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+92 51 9261592

Email address

drfarhan992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-03, 1400/02/13

Expected recruitment end date

2021-08-31, 1400/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

High dose solumedrol in patients with severe Covid-19 infection

Public title

Solumedrol in Covid-19 infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Provide written informed consent Subjects age > 18 years at the time of signing the Informed Consent Form. Male or Female Must have a clinical diagnosis of COVID-19, with at least one clinical symptom (e.g., fever $\geq 38^{\circ}\text{C}$, fatigue, cough) and a positive result by the reverse-transcription polymerase chain reaction (RT-PCR) testing or equivalent. Individuals with severe COVID-19 symptoms according to Berlin Criteria Hospitalized patients and on Mechanical Ventilation Patients requiring FiO_2 of 0.5 or more and a PEEP of 5 mmHg or more Ability to provide informed consent or an authorized representative can sign the informed consent

Exclusion criteria:

Pregnant females Patients with HIV infection. Patients with active tuberculosis or a history of treatment for pulmonary tuberculosis Patients with a CrCl of less than 30 ml/minute Patients with heart disease and an ejection fraction of 30% or less Patients with advanced liver disease Patients allergic to methylprednisolone

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized using a "simple" randomization method with "individuals" considered as a single unit. A table of random numbers will be generated using "<https://www.randomizer.org/>". One set of patients will be labeled as "controls" while the other group will be labeled as the "Interventional Group". Patients and caregivers (ICU nurse) will be blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and caregivers will be blinded. Blinding is done by the primary investigator who will label the infusion sets according to the randomization table provided by "<https://www.randomizer.org/>". Both groups will receive 100 ml Saline infusion labeled according to the table provided by the randomization site. Control will receive Saline, while those receiving an active drug will be infused solumedrol added to the 100 ml saline.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shaheed Zulfiqar Ali Medical University

Street address

G-8/3

City

Islamabad

Postal code

46000

Approval date

2021-04-28, 1400/02/08

Ethics committee reference number

No. F. 1-1/2015/ERB/SZABMU/771

Health conditions studied**1****Description of health condition studied**

COVID-19 infection

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

In-hospital mortality

Timepoint

28 days

Method of measurement

Pre-designed Performa

Secondary outcomes**1****Description**

Duration of hospital stay

Timepoint

28 days

Method of measurement

Predesigned performa

2

Description

Improvement in lung mechanics

Timepoint

28 days

Method of measurement

predesigned performa

3

Description

improvement in inflammatory markers

Timepoint

28 days

Method of measurement

predesigned performa

4

Description

incidence of secondary infections

Timepoint

28 days

Method of measurement

predesigned performa

Intervention groups

1

Description

Control group: Patients will receive 100 ml saline once daily in addition to the standard therapy for three days. Saline will contain 150 mmol/L sodium and 150 mmol/L chloride and an osmolality of 308 mOsm/L. Brand Name: UNISOL-NS (UNISA Pharmaceuticals Industries Ltd)

Category

Placebo

2

Description

Intervention group: Patients will receive 1000 mg methylprednisolone (Solumedrol injection, manufactured by Pfizer Pharmaceuticals Ltd). The injection will be diluted in 90 ml Saline to make up a total of 100 ml solution. Patients will receive the injection of three consecutive days once daily infusion over 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pakistan Institute of Medical Sciences, Islamabad

Full name of responsible person

Ahmed Farhan

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Sponsors / Funding sources

1

Sponsor

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

Pakistan Institute of Medical Sciences, Islamabad

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

Pakistan Institute of Medical Sciences

Full name of responsible person

Ahmed Farhan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data regarding the patient's demographics, response to the treatment, and the outcome may be shared.

When the data will become available and for how long

Data will be available as soon as the study is ready to be published.

To whom data/document is available

All healthcare workers and researchers can access the data.

Under which criteria data/document could be used

Data will be shared via email.

From where data/document is obtainable

Data will be accessible on request via email.

What processes are involved for a request to access data/document

Data may be shared via email. Anyone who is a healthcare personal or a researcher can get a soft copy of the data via email.

Comments