Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 severeCOVID-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

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Pakistan

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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 ≥38°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 FiO2 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 Pharamaceuticals 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

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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
Internal Medicine
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Person responsible for updating data

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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