

Comparing two medications (dexamethasone and methylprednisolone high dose) for the treatment of pneumonia in patients with COVID-19

Submission date 26/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/01/2024	Condition category Infections and Infestations	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

To date, dexamethasone (a type of medicine called steroid [corticosteroid]) has shown to decrease mortality (death rate) in patients who require oxygen, especially those with invasive mechanical ventilation. However, it is unknown if another corticosteroid can be used, and the optimal dose and duration to achieve a better clinical outcome. The aim of this study is to compare the differences in clinical outcome and laboratory results in hospitalized patients with severe SARS-CoV-2 pneumonia treated with dexamethasone versus patients treated with high-dose methylprednisolone.

Who can participate?

Adults aged over 18 with confirmed COVID-19 and suffering from pneumonia

What does the study involve?

Patients are treated with either dexamethasone or methylprednisolone according to the protocol set by the clinic. Recovery time is measured using patient records.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Clínica Medellín (Colombia)

When is the study starting and how long is it expected to run for?

April 2020 to November 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Miguel Pinzón

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

20-33686

Study information

Scientific Title

Dexamethasone vs methylprednisolone high dose for COVID-19 pneumonia

Study objectives

To date, dexamethasone has shown a decrease in mortality in patients who require oxygen, especially those with invasive mechanical ventilation. However, it is unknown if another corticosteroid can be used, the optimal dose and its duration, to achieve a better clinical outcome. The study's objective was to compare the differences in clinical outcome and laboratory results in hospitalized patients with severe SARS-CoV-2 Pneumonia treated with dexamethasone at 6 mg doses versus patients treated with high-dose methylprednisolone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/04/2020, the Clinica Medellin ethics committee (A Sede Occidente: Carrera 65 B # 30 - 95, Colombia; +57 (0)4 4020990 - opt 1 ext 617; investigacionesiqs@clinicamedellin.com), ref: 04-2020

Study design

Single-centre observational cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection) related pneumonia

Interventions

From 11/06/2020, patients were treated with dexamethasone 6 mg QD for seven to 10 days if they required oxygen.

After 15/09/2020, the clinic's protocol was modified to use methylprednisolone 250 to 500 mg every day for 3 days with a subsequent change to oral prednisone 50 mg every day for 14 days.

The researchers will compare the differences in clinical outcome and laboratory results in hospitalized patients with severe SARS-CoV2 pneumonia treated with dexamethasone at 6 mg doses versus patients treated with high-dose methylprednisolone.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dexamethasone, methylprednisolone

Primary outcome(s)

Recovery time measured in days using patient records; recovery time determined as the time until hospital discharge when each of the following criteria were met: decrease in laboratory severity markers, improvement in symptoms, decrease in oxygen requirement until nasal cannula or supplementary oxygen removal, and at least two doses of the respective treatment have been received

Key secondary outcome(s)

Respiratory health measured using arterial blood gas results during the period of hospitalization

(Cytokine Release Syndrome (CRS) defined as ventilatory impairment plus two of the following: C-reactive protein (CRP) greater than 10 mg/dl, serum ferritin greater than 1000 ng/ml, D-dimer greater than 900 ng/ml)

Completion date

15/11/2020

Eligibility

Key inclusion criteria

1. Over 18 years of age
2. Hospitalized with COVID-19 pneumonia confirmed by positive Real-Time Reverse Transcription Polymerase Chain Reaction for SARS-CoV2 (RT-PCR SARS-CoV-2) by Berlin protocol
3. Radiological confirmation of pneumonia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

213

Key exclusion criteria

1. Contraindications associated with corticosteroids
2. Dissent for medical management
3. Death in the first 24 hours
4. Patient in palliative care or with a life expectancy of fewer than 6 months
5. If the patient required admission to the ICU and did not receive at least two doses of the corticosteroid
6. If the patient receives at least two doses of methylprednisolone but did not continue with

prednisone, they were not included, but their outcome continued to be monitored
7. Patients who also received less than 2 days of dexamethasone treatment were withdrawn from study follow-up

Date of first enrolment

11/06/2020

Date of final enrolment

31/10/2020

Locations

Countries of recruitment

Colombia

Study participating centre

Clínica Medellín

Cra 65 B #30-95

Medellín

Colombia

050020

Sponsor information

Organisation

Clínica Medellín - Grupo Quirónsalud

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Miguel Alejandro Pinzón (alejandropinzon01@yahoo.es) with prior

authorization by the ethics and research committee of the Medellin clinic. All data can be reviewed except for patient identification.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/05/2021	14/03/2022	Yes	No
Dataset		25/05/2021	03/01/2024	No	No
Protocol file			02/12/2020	No	No