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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

Registration date
27/11/2020

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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 asteroid [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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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)

Overall study start date
01/04/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
216

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
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Sponsor information

Organisation

Clínica Medellín - Grupo Quirónsalud

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.clinicamedellin.com/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2020

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?
Protocol file			02/12/2020	No	No
Results article		25/05/2021	14/03/2022	Yes	No

Dataset	25/05/2021	03/01/2024	No	No