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Influence of geographic altitude on the evolution of severe cases of COVID-19 in Ecuador

Submission date
21/06/2021

Recruitment status
No longer recruiting

Registration date
16/08/2021

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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.
COVID-19 ranges from mild disease to severe cases of pneumonia, which can be accompanied by a strong inflammatory reaction (acute respiratory distress syndrome or ARDS), multiorgan failure and death. Some factors have been found to influence disease in these patients, including age and the coexistence of other diseases (comorbidities) like obesity, high blood pressure and diabetes. Constant exposure to decreased levels of oxygen (hypoxia) can also lead to a variety of clinical conditions and to physiologic adaptations that allow people living in these environments to reduce their oxygen demand by improving efficiency at a cellular level. During critical illness, it is proposed that natives of high-altitude cities have a higher oxygen utilization efficiency and an advantage over severe patients living at sea level. The aim of this study is to determine if a high geographic altitude affects patients diagnosed with severe cases of COVID-19 requiring oxygen support (mechanical ventilation).

Who can participate?
Patients who are 18 years old or older with a confirmed diagnosis of COVID-19, admitted to the intensive care units between March 2020 and October 2020 in Ecuadorian cities located in a geographical altitude of 2500 m or at sea level, and requiring invasive oxygen support (mechanical ventilation)

What does the study involve?
The study involves the gathering and analysis of data including demographic variables, coexistence of other diseases (comorbidities), symptoms and signs prior to hospital admission, severity scores and initial management. Additionally, laboratory, vital signs (hemodynamic variables), and respiratory variables (mechanical ventilation) will also be collected.

What are the possible benefits and risks of participating?
There will no direct contact with the patients and the information required will be collected using medical registries complying with privacy protocols. All data will be gathered anonymously, and each patient will have a code assigned to them. The data will not be used outside the hospital or research group. Therefore, there are no possible risks to the patients participating in this study. However, the information will become useful and beneficial for treatment and prognosis in future patients.

Where is the study run from?
Hospital de Especialidades Eugenio Espejo (Ecuador)

When is the study starting and how long is it expected to run for?
April 2020 to July 2021

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Manuel Jibaja
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
No. 015-2020 (Ecuadorian Ministry of Health)

Study information

Scientific Title
Influence of geographic altitude on the evolution of COVID-19 patients admitted to the intensive care units (ICUs) in Ecuador

Study objectives
A geographic altitude of 2500 m or more above sea level affects the evolution of patients diagnosed with COVID-19 admitted to the ICU and requiring mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2021, Ecuadorian Ministry of Health Ethics Committee (Av. Quitumbe Ñan y Av. Amaru Ñan 170146, Quito, Ecuador; +593 (0)23814400; cnbs@msp.gob.ec); ref: 015-2020

Study design
Multicentre longitudinal case-control observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Severe cases of COVID-19 (SARS-CoV-2 infection) requiring ICU and mechanical ventilation

Interventions
Retrospective data collection from the cohort of patients diagnosed with severe COVID-19 between the months of March to July 2021, admitted to Intensive Care Units of hospitals located in Ecuadorian cities with a geographical altitude of 2500 m above sea level and at sea level. Information on demographic variables, comorbidities, symptoms, and signs prior to admission to the ICU, severity indexes, and initial management in the ICU will be collected. Laboratory data, hemodynamic variables, and respiratory variables on mechanical ventilation will also be collected, the latter at admission and after 24 h. Data on withdrawal of mechanical ventilation, specific treatments, complications, and prognosis are collected.

Intervention Type
Other

Primary outcome(s)
Mortality (%) of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point

Key secondary outcome(s))
1. Duration of mechanical ventilation (in days) of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
2. Duration of ICU admission and duration hospitalization (in days) of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
3. PaO2/FiO2 index of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
2. Mortality risk factors of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
3. Comorbidities of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
4. Symptoms and signs prior to admission to the ICU of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
5. Severity indexes of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
6. Initial management of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
7. Laboratory data of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
8. Hemodynamic variables of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
9. Respiratory variables on mechanical ventilation taken on admission and after 24 h in patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
10. Withdrawal of mechanical ventilation from patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
11. Specific treatments received by patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
12. Complications in patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point
13. Prognosis of patients diagnosed with severe COVID-19 between the months of March to July 2021 measured from retrospectively collected hospital data at a single time point

Completion date
01/07/2021

Eligibility

Key inclusion criteria
1. Patients (men and women) 18 years old or older
2. Diagnosed with COVID-19 by RT-PCR
3. Admitted to ICUs in Ecuador located in cities with geographic altitude of 2500 ms above sea

level and at sea level
4. Need for mechanical ventilation as part of their management

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients younger than 18 years of age
2. Patients admitted to ICU for a diagnosis other than COVID-19 and also required mechanical ventilation
3. Foreign patients

Date of first enrolment
12/02/2021

Date of final enrolment
01/05/2021

Locations

Countries of recruitment
Ecuador

Study participating centre
Hospital Eugenio Espejo
Av. Gran Colombia
Quito
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Study participating centre
Hospital Metropolitano
Av. Mariana de Jesús s/n

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Ecuador
170521

Study participating centre
Hospital de Especialidades Portoviejo
Calle 15 de Abril y Av. Uruguay
Sector Las Tres Marías
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Study participating centre
Hospital de Especialidades José Carrasco Arteaga
José Carrasco Arteaga entre Popayán y Pacto Andino
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Hospital de Especialidades Eugenio Espejo

Organisation
Universidad San Francisco de Quito

ROR
https://ror.org/01r2c3v86

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 Iván Sisa(isisa@usfq.edu.ec)
Anonymized demographic data and clinical data will become in January 2022, for two years to researchers, by RedCap, for secondary analyses.
Informed consent for this study was not obtained. This is a retrospective study of clinical data. Patients/next of keens signed the hospital's consent for treatment. There are no ethical restrictions, as ethical approval was obtained for the study and data is anonymized.

IPD sharing plan summary
Available on request