

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/08/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/08/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A sample size calculation will not be performed; rather, the maximum possible number of patients meeting the inclusion criteria will be recruited.

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

Ecuador

170136

Study participating centre

Hospital Metropolitano

Av. Mariana de Jesús s/n

Quito

Ecuador

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Study participating centre

Hospital de Especialidades Portoviejo

Calle 15 de Abril y Av. Uruguay

Sector Las Tres Marías

Portoviejo

Ecuador

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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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Av. Juan Agnoleto y By pass

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Study participating centre
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Organisation
Universidad San Francisco de Quito

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Sponsor type

University/education

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ROR

<https://ror.org/01r2c3v86>

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

30/11/2021

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