ISRCTN78284710 https://doi.org/10.1186/ISRCTN78284710

Clinical characteristics and outcomes of patients with COVID-19 on mechanical ventilation in Argentina

Submission date
10/02/2021

Recruitment status
No longer recruiting

Registration date
03/03/2021

Overall study status
Completed

Last Edited
28/06/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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.
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.
Knowledge about the epidemiology, management and outcomes of COVID-19 patients on invasive mechanical ventilation in low and middle income countries (LMICs) is scarce and fragmented. The aim of this study is to describe the practice of mechanical ventilation in patients with COVID-19 in Argentina.

Who can participate?
Patients older than 18 years with COVID-19 admitted to the Intensive Care Unit and requiring mechanical ventilation

What does the study involve?
The study involves the collection of epidemiological variables, mechanical ventilation variables, certain treatments applied and complications, and identification of independent prognostic (predictive) factors of mortality (death). The main outcome variable is hospital mortality; secondary outcomes are 28-day mortality, duration of mechanical ventilation, and duration of ICU and hospital stays.

What are the possible benefits and risks of participating?
Since this is an observational study, patients are not exposed to any risk or benefit.

Anonymization of patient data is performed by assigning numeric codes. When finished and published, the main findings and conclusions might help to guide the management of COVID-19 and eventually improve healthcare management in future waves of the pandemic.

Where is the study run from?
1. Hospital Interzonal de Agudos San Martin de La Plata (Argentina)
2. Argentine Society of Intensive Care Medicine (SATI) (Argentina)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04611269

Protocol serial number
01

Study information

Scientific Title
Clinical characteristics and outcomes of patients with COVID-19 on mechanical ventilation in Argentina: a prospective, multicenter cohort study

Acronym
SATICOVID19

Study objectives
The main objective of the present study is to determine ICU and in-hospital mortality associated with COVID-19 infection and its independent predictors, in patients admitted to adult ICUs in Argentina with a requirement for mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/04/2020, Comité De Ética en Investigación Hospital San Martin De La Plata (CEI-HSMLP, Postal address: 1900; +54 (0)92216073261; ceihsmlaplata@gmail.com), ref: HSMLP2020/0021

Primary study design
Observational

Study design
Prospective cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Epidemiological data, comorbidities, previous signs or symptoms of COVID-19 are collected. On admission, severity of disease scores, laboratory management data, blood gases and acid-base chemistry, respiratory and mechanical ventilation management, and complications (development of ARDS, septic shock, acute kidney injury, thromboembolic events, infections and septic shock) will be recorded. If patients die, the cause of death will be recorded. Treatments

administered by attending physicians will be registered. Dates of hospital and ICU admission, of death and/or discharge will be recorded. No intervention will be administered. Follow-up will continue until death or ICU/hospital discharge.

Intervention Type
Other

Primary outcome(s)
Hospital mortality: death of a patient (categorical binary data, 1 = nonsurvivor; and 0 = survivor) occurring at any time and in any site during hospitalization

Key secondary outcome(s)
1. 28-day mortality: death of a patient (categorical binary data, 1 = nonsurvivor; and 0 = survivor) occurring in any site of the hospital between hospital admission and day 28
2. Duration of mechanical ventilation: number of days of invasive mechanical ventilation measured as continuous data (in days), as the difference between the date of weaning from mechanical ventilation and the date of endotracheal intubation
3. Length of ICU stay: number of days measured as continuous data (in days), as the difference between the date of ICU discharge and the date of ICU admission
4. Length of hospital stay; number of days measured as continuous data (in days), as the difference between the date of hospital discharge and the date of hospital admission

Completion date
10/01/2021

Eligibility

Key inclusion criteria
Consecutive adult patients admitted to participating ICUs who require mechanical ventilation and present confirmed COVID-19

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1909

Key exclusion criteria
Patients with severe respiratory infections/pneumonia due to another proven etiology

Date of first enrolment

30/03/2020

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Argentina

Study participating centre
Hospital Interzonal de Agudos, Gral san Martin de la Plata
Avenida 1 y 70
La Plata
Argentina
1900

Sponsor information

Organisation
Sociedad Argentina de Terapia Intensiva (SATI)

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data might be available for 1 year after the date of the study publication. This will require the consent of the six principal researchers, and the aim of the request and statistical plan should be provided. The data are already anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2021	28/06/2022	Yes	No
Protocol file	version 1		01/04/2021	No	No
Protocol file	version 2		01/04/2021	No	No