ISARIC

ISARIC (International Severe Acute Respiratory and Emerging Infections Consortium)

A global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious disease

Analysis Plan for ISARIC International COVID-19 Patients

Please complete the following sections:

Title of proposed research
Influence of nutrition status on COVID-related outcome
Version: (Date: Day/Month/Year)
1.0 (19/01/2021)
Working Group Chair (name, ORCID ID, email, institution, country)
Jean-Charles Preiser, 0000-0003-3163-0390, Jean-Charles.Preiser@erasme.ulb.ac.be, CUB-Hopital Erasme, Belgium
[1]Working group co-chair (name, ORCID ID, email, institution, country)
Marianna Arvanitakis, Marianna.Arvanitaki@erasme.ulb.ac.be, CUB-Hopital Erasme, Belgium
Statistician (name, ORCID ID, email, institution, country)
Jason Bouziotis, 0000-0001-6656-451X, Jason.Bouziotis@erasme.ulb.ac.be, CUB-Hopital Erasme, Belgium

[1] Either chair and/or co-chair are based in an institution in an LMIC. If you would like to be connected with an eligible co-chair please let us know at ncov@isaric.org.

Final draft SAPs will be circulated to all ISARIC partners for their input with an invitation to participate. ISARIC can help to set up collaborator meetings; form a working group; support communications; and accessing data. Please note that the details of all approved applications will be made publicly available on the ISARIC website. Please complete all sections of this form fully and return to **ncov@isaric.org**

Introduction

This document details the initial analysis plan for publication on a subset of COVID-19 patients in the global cohort in the ISARIC database, as of 20 NOV 2020. There are currently 42 countries (as of 20 NOV 2020) contributing data and these have so far contributed data on over 122,000 patients. This data will represent the global experience of the first 9 months of this pandemic.

Participatory Approach

All contributors to the ISARIC database are invited to participate in this analysis through review and input on the statistical analysis plan and resulting publication. The outputs of this work will be disseminated as widely as possible to inform patient care and public health policy, this will include submission for publication in an international, peer-reviewed journal. ISARIC aims to include the names of all those who contribute data in the cited authorship of this publication, subject to the submission of contact details and confirmation of acceptance of the final manuscript within the required timelines, per ICMJE policies and the ISARIC publication policy.

Research Plan

Summary of Research Objectives
Compare COVID-19-related mortality according to underweight status and malnutrition, before and after adjustments for known demographic confounders.
Proposed Target Population
Patients hospitalized for COVID-19 infection worldwide, requiring or not a stay in an intensive care unit (ICU) or high-dependency unit.
Clinical Questions/Descriptive Analyses
Descriptive statistics (count, mean (SD), median (IQR), percentages): - Age (year) - Sexe (F/M) - BMI (kg/m²) - Underweight (if BMI<18.5 and age≤65, or if BMI<20.5 and age>65) (Yes/No) - Malnutrition (Yes/No) - ICU or High Dependency Unit admission (Yes/No) - Length of stay (days) - Death (Yes/No)

Planned Statistical Analyses, Methodology and Representation
Survival analysis will be performed with death as primary outcome. Time will be considered as the length of stay in days (outcome date – admission date). We will compare outcome according to underweight and malnutrition and possible confounding factors. For that, we will compare time-to-event among different groups (sexe, underweight, malnutrition, ICU admission) with Kaplan Meier curves and Log-rank test. We will also use Cox models to calculate hazard ratios of death for age, sexe, BMI, underweight, malnutrition and ICU admission. Finally, we will compute a multivariable Cox model with explanatory variables and choose the best model based on Akaike information criterion (AIC).
Handling of Missing Data
We will only be able to include patients for which we can calculate a BMI and/or a record regarding the presence of malnutrition and a length of stay, and with an outcome status. We will report the number of patients without this information.

Other Information

Provide details of the timelines for dissemination of research findings.

References

Please list any relevant references.