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Occupational health and safety among health care personnel in a COVID-19 pandemic

Submission date
14/04/2020

Recruitment status
No longer recruiting

Registration date
15/04/2020

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Other

[X] 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.

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 March 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.

Since the appearance of the Covid-19 virus in the Chinese region of Wuham at the end of 2019, its expansion has been unstoppable, currently becoming a pandemic that dramatically affects our country and has become a major health problem. Since the virus landed in Spain, its evolution has gone from isolated cases to community transmission and has continued throughout the country since mid-March.
At the health level, the most important thing is the detection of the infected patient as early as possible in order to generate isolation, and isolation or confinement zones have been created both in the emergency services and in hospitalization areas in which the sanitarians have to remain a certain number of hours within them. In addition, their care must be carried out through personal protection equipment (PPE) with more or less protection.
Working in these isolation areas or Covid zones (ZoCod) PPEs provide health professionals with security to carry out their work, but at the same time generates physiological and psychological stress that can affect their professional performance.

Work similar to that proposed in research laboratory settings and in a short time in which gender, muscle mass, bone mass, height and physical activity carried out by the individual can determine muscle fatigue and have been developed consequently the performance of these professionals. However, this work is intended to be carried out under real conditions for workers, both at emergency care levels and at hospitalization levels.

Who can participate?
Workers of the Río Hortega Hospital and the Convalescence Hospital for COVID19 in Valladolid.

What does the study involve?
Volunteers undergo a structured and objective evaluation. Respiratory rate, saturation, heart rate, blood pressure, temperature, weight, height, medication intake, and baseline pathology are measured, and a blood test is performed.
The volunteer is equipped with PPE against biological risks (some use N95 respirators and others FFP2 face mask randomly) and enter the treatment unit of COVID19.
At 4 hours the workday ends with PPE, once decontaminated, the same determinations that were made at baseline are repeated: respiratory rate, saturation, heart rate, blood pressure, temperature and a blood test is performed. They are also asked about the presence of headache, skin lesions, etc.
Both N95 respirators and FFP2 face masks offer the same level of protection and are approved in both hospital procedures.

What are the possible benefits and risks of participating?
Through this study, the researchers intend to know how health workers physically and metabolically tolerate PPE and see if working conditions can be improved.
Volunteers present the risks inherent in their own work, whether or not they participate in the study.

Where is the study run from?
Hospital de Convalecencia de la Feria y Hospital Universitario Rio Hortega, Valladolid (Spain).

When is the study starting and how long is it expected to run for?
April 2020 for one week.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Francisco Martín-Rodríguez, fmartin@saludcastillayleon.es

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V_01_2020_ref.03.v_02

Study information

Scientific Title
Predictive value of biological, physiological and analytical biomarkers with the use of personal protection equipment in COVID-19: observational, prospective, analytical, intervention and multicenter study

Acronym
COVVA

Study objectives
Evaluate the prognostic capacity of different parameters (PAS, PAD, T, SpO2, HR, etc ..), analytical biomarkers (pH, PaCO2, HCO3, Cl, K, Ca, Cl, Lactate, creatinine, BUN, etc.), and life style habits, separately and at the joint level obtained at the COVID19 treatment unit, to predict metabolic fatigue in workers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/04/2020, CEIC Área de Salud de Valladolid Oeste (Hospital Universitario Río Hortega, 47012 Valladolid (Valladolid); +34 983 420 400; rconvi@saludcastillayleon.es), ref: PI075-20

Study design
Observational prospective cross-sectional cohort analytical intervention and multicenter study

Primary study design

Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Complications or secondary effects derived from the use of personal protective equipment against biological risks

Interventions
Volunteers (workers in a COVID19 treatment unit) undergo a structured and objective evaluation. Physiological variables (respiratory rate, saturation, heart rate, systolic and diastolic blood pressure and temperature) are collected, health variables are also collected (previous illnesses, taking medication, COVID19 symptoms, weight and height) and an analytical test is performed of blood (venous by extraction in the cephalic vein of the left arm) to obtain the following parameters: pH, PaCo2, PO2, HCO3, Na, K, Cl, Ca, Hematocrit, hemoglobin, lactate, glucose, urea, BUN and creatinine.

Volunteers are randomized, some wear N95 respirators and others wear an FFP2 mask with an exhalation valve, are fully equipped with personal protective equipment and enter the COVID19 area. At 4 hours of work they leave, are decontaminated and the same determinations that have been made on a basal basis are repeated. They are also asked if they have a headache (not due to the pressure of the glasses or face shield), wounds or chafing, and how they have felt at the level of tiredness.
At this time, the observation will end.

Intervention Type
Mixed

Primary outcome measure
1. Respiratory rate, assessed by clinical observation at baseline and at the end of the 4-hour workday
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor at baseline and at the end of the 4-hour workday
3. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline and at the end of the 4-hour workday
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor at the start of the study and at the end of the 4-hour workday
5. Tympanic temperature evaluated using a Braun ThermoScan® PRO 6000 model at baseline and at the end of the 4-hour workday
6. Weight, with the TANITA BC 545-N scale at baseline

8. Size, with the SECA 206 tape measure at baseline
9. Analytical biomarkers: pH, pCO2, pO2, cHCO3-, BE (ecf), cSO2, Na +, K +, Ca ++, Cl-, TCO2, Agap, AGapK, Hct, Hb, BE (b), Glu , Lac, BUN, Urea and Crea, evaluated using COPD Siemens Healthcare at baseline and at the end of the 4-hour workday
10. Medical history of interest, through a structured questionnaire at baseline
11. Level of physical activity using the IPAQ questionnaire at baseline

Secondary outcome measures
1. Headache presence measured using self-report at the end of the 4 hours of working with the equipment
2. Presence of serious adverse events during the use of protective equipment measured using self-report at the end of the 4 hours of working with the equipment
3. Presence of chafing, wounds, etc., due to the use of protective equipment measured using self-report at the end of the 4 hours of working with the equipment
4. Perception of the state of physical fatigue at the end of the working day with the protective equipment measured using self-report at the end of the 4 hours of working with the equipment
5. Time in COVID19 zone measured using self-report at the end of the 4 hours of working with the equipment

Overall study start date
01/04/2020

Completion date
22/04/2020

Eligibility

Key inclusion criteria
1. Workers (doctors, nurses and assistants) in the COVID19 treatment unit with the biological risks training course
2. Aged over 18 years
3. Provide informed consent

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Pregnant
2. Psychiatric pathology
3. Do not sign the informed consent
4. Not to be part of the HURH and Covid-Fair staff during the month of April

Date of first enrolment
16/04/2020

Date of final enrolment
17/04/2020

Locations

Countries of recruitment
Spain

Study participating centre
Hospital de Convalencia de la Feria para COVID19 (COVVA)
Avda. Ramón Pradera, 3
Valladolid
Spain
47009

Study participating centre
Hospital Universitario Rio Hortega
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Sponsor information

Organisation
University of Valladolid

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Sponsor type
University/education

Website
http://www.uva.es/export/sites/uva/

ROR
https://ror.org/01fvbaw18

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
There is a study protocol and analysis plan that can be sent upon reasonable request.

The research team will promote the dissemination of the results obtained in various scientific publications:
1. American Journal of Medicine
2. Critical Care Medicine
3. Emergencies
4. Intensive Care Medicine
5. Prehospital & Emergency Care
6. Resuscitation
If external funding is obtained, communications could be sent to the main international emergency and emergencies forums

Intention to publish date
20/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (F. Martín-Rodríguez, fmartin@saludcastillayleon.es). Statistical data will be available from the end of the data collection phase for 4 years. The data may be shared with researchers carrying out similar studies, provided that the exchange of information is mutual, by

sending the anonymized data of patients. Patients will have signed informed consent for data sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		04/01/2021	12/06/2023	Yes	No