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An investigation of malnutrition, obesity, diabetes, high blood pressure and severe COVID-19 in Italy

Submission date
25/12/2020

Recruitment status
No longer recruiting

Registration date
30/12/2020

Overall study status
Completed

Last Edited
31/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[X] 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.

The prevalence in the general population of obesity, diabetes, hypertension (high blood pressure) and malnutrition (poor diet) is high, therefore it is useful to investigate the clinical significance when these conditions are present in patients with COVID-19.

Who can participate?
Patients admitted to different Italian hospitals for serious COVID-19 disease.

What does the study involve?
The study will examine the medical records of patients with serious COVID-19 to find health and

lifestyle factors that are related to severe COVD-19. If the records do not contain all the required information the participant may have a telephone interview to gather missing information.

What are the possible benefits and risks of participating?
The benefit of participating is helping with the research. This study could provide useful information for the prognosis and treatment of this disease and could promote better management of the disease. There are no risks associated with participating.

Where is the study run from?
University of Palermo (Italy).

When is the study starting and how long is it expected to run for?
December 2020 to June 2021.

Who is funding the study?
University of Palermo (Italy)

Who is the main contact?
Prof. Silvio Buscemi, MD, silvio.buscemi@unipa.it

Contact information

Type(s)
Scientific

Contact name
Prof Silvio Buscemi

ORCID ID
https://orcid.org/0000-0003-0730-7649

Contact details
University of Palermo - PROMISE department
Unit of Clinical Nutrition; AOU Policlinico "P. Giaccone"
Piazza delle Cliniche, 2
Palermo
Italy
90127
+39 91 6552251
silvio.buscemi@unipa.it

Additional identifiers

Protocol serial number
02/2020

Study information

Scientific Title

Malnutrition, obesity, diabetes, hypertension and severe COVID-19 in Italy

Acronym
MODIeCOSe in Italia

Study objectives
The prevalence in the general population of obesity, diabetes, hypertension and malnutrition is high. It is useful to investigate the association of these diseases with severe COVID-19 to improve prognosis and treatment in the hospital environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2020, Palermo 1 Ethics Committee (AOU Policlinico "P. Giaccone"; via del vespro 129 -90127 Palermo, Italy; +39 91 6555210/5211; bioetica@policlinico.pa.it), ref: 11/2020

Primary study design
Observational

Study design
Longitudinal observational retrospective multicenter study

Study type(s)
Other

Health condition(s) or problem(s) studied
To investigate the association between obesity, diabetes, hypertension and malnutrition with severe COVID-19 outcome (SARS-CoV-2 infection) in hospital settings

Interventions
Patients must fulfil the inclusion criteria for entry. Data will be extracted from the medical records and databases of each center. In the case of patients who have previously given written consent to be contacted, the evaluation/completion of any missing data can be ensured through a telephone interview with the patient or caregiver. Data will be made anonymous and identified through a code. The code will be linked to each patient's medical record in a guarded list of each center. The data will flow into a single Excel database at the main center.

Intervention Type
Other

Primary outcome(s)
Measured using patient records (and a telephone interview if required) at a single time point:
1. Demographics
1.1. Age
1.2. Ethnicity
1.3. Current or previous work activity
1.4. Self-sufficient patient (yes/no)
1.5. In a nursing home (yes/no)
1.6. Caregiver (yes/no)
2. Hospitalisation and outcome

2.1. Duration of hospitalization (days)
2.2. Transferred to resuscitation (yes/no)
2.3. Recovery (yes/no)
3. Vaccinated for influenza or pneumococcus (yes/no)
4. Anthropometric data
4.1. Height (cm)
4.2. Weight (kg)
4.3. Waist circumference (cm)
5. Medication history before admission
6. Hematology at entry and near discharge
6.1. Leukocytes (x10(9)/L)
6.2. Red blood cells (x10(12)/L)
6.3. Hemoglobin - HB (g/dl)
6.4. Hematocrit - Hct (%)
6.5. MCV (f/L)
6.6. Platelets (x10(9)/L)
6.7. Lymphocytes (x10(9)/L)
6.8. Neutrophils (x10(9)/L)
7. Lab values at entry and near discharge
7.1. Blood glucose (mg/dl)
7.2. HbA1c (%)
7.3. Creatinine (mg/ml)
7.4. Total cholesterol (mg/dl)
7.5. HDL cholesterol (mg/dl)
7.6. Triglycerides (mg/dl)
7.7. ALT (U/L)
7.8. AST (U/L)
7.9. GGT (U/L)
7.10. Albunemia (%)
7.11. Total proteins (g/dl)
7.12. eGFR IL-6 (pg/ml)
7.13. C-reactive protein (mg/dl)
7.14. CK (mg/dl)
7.15. LDH (U/L)
7.16. Ferritin (ng/ml)
8. Blood gas values at entry and near discharge
8.1. PaO2
8.2. PaCO2
8.3. FiO2
8.4. PH
8.5. Lactates
8.6. HCO3- SO2
8.7. Oxygen therapy (y/n)
8.8. PEEP
9. Therapy during stay
9.1. Paracetamol
9.2. Cortisone
9.3. Antibiotic (Macrolide [azithromycin], cephalosporin, quinolone)
9.4. Heparin
9.5. Chloroquine/Hydroxychloroquine
9.6. Cholecalciferol
9.7. Artificial nutrition

9.8. Other
10. Previous pathologies
10.1. Diabetes mellitus
10.2. Arterial hypertension
10.3. Ischemic heart disease
10.4. Chronic heart failure
10.5. Smoking
10.6. Atrial fibrillation
10.7. Neoplasms
10.8. Chronic obstructive pulmonary disease
10.9. Bronchial asthma
10.10. Chronic renal failure
10.11. Stroke
10.12. Pulmonary embolism
10.13. Congenital heart disease
10.14. Other

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Hospitalized patients
2. Proven COVID-19 disease
3. Aged 18 and above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Italy

Study participating centre
University of Palermo
Department PROMISE
Unit of Clinical Nutrition
AOU Policlinico “P. Giaccone”
Piazza delle Cliniche, 2
Palermo
Italy
90127

Study participating centre
Ospedale Sant’Anna di Como
Struttura Semplice Dipartimentale di Endocrinologia
Nutrizione Clinica e Obesità
Via Ravona
San Fermo della Battaglia (CO)
Italy
22042

Study participating centre
IRCCS Policlinico San Donato
Servizio di Nutrizione Clinica e Prevenzione Cardiovascolare
Piazza Edmondo Malan, 2
San Donato Milanese (MI)
Italy
20097

Study participating centre
Università di Padova
Clinica Medica 3
Azienda Ospedaliera Università Padova
Via Giustiniani, 2
Padova (PD)
Italy
35128

Study participating centre
Università di Pisa
UOC di Endocrinologia
Azienda Ospedaliero-Universitaria Pisana
Via Paradisa, 2
Pisa
Italy
56124

Study participating centre
Università di Pisa
SD Medicina Interna ad indirizzo Immuno-Endocrino
Azienda Ospedaliero-Universitaria Pisana
Via Paradisa, 2
Pisa
Italy
56124

Study participating centre
Università degli Studi di Roma "Tor Vergata"
Dipartimento di Medicina dei Sistemi
Via Montpellier, 1
Roma
Italy
00133

Study participating centre
Università "Sapienza" di Roma
Dipartimento di Medicina Sperimentale
UOC Diabetologia Universitaria Ospedale Santa Maria Goretti
Via Guido Reni
Latina
Italy
04100

Study participating centre
Università Magna Graecia di Catanzaro
UO Malattie Infettive e tropicali - Azienda Ospedaliero Universitaria "Mater Domini"
Viale Tommaso Campanella, 115
Catanzaro

Italy
88100

Study participating centre
Azienda Ospedaliera di Rilievo Nazionale e di Alta Specializzazione Garibaldi
PO Garibaldi-Nesima - UOC Geriatria
Via Palermo, 636
Catania
Italy
95122

Study participating centre
Università di Palermo
Dipartimento PROMISE
Medicina interna COVID, AOU Policlinico “P. Giaccone”
Via delle Cliniche, 2
Palermo
Italy
90127

Study participating centre
Università di Palermo
Dipartimento PROMISE
Malattie Infettive, AOU Policlinico “P. Giaccone”
Via delle Cliniche, 2
Palermo
Italy
90127

Study participating centre
Università di Palermo
Dipartimento PROMISE
Pneumologia COVID, AOU Policlinico “P. Giaccone”
Via delle Cliniche, 2
Palermo
Italy
90127

Study participating centre
ARNAS Civico di Cristina Benfratelli
Pneumologia COVID

P.zza Nicola Leotta, 4
Palermo
Italy
90127

Study participating centre
Ospedale Madonna dell'Alto
Medicina Interna COVID
Contrada Sant Elia
Petralia Sottana (PA)
Italy
90027

Sponsor information

Organisation
University of Palermo

ROR
https://ror.org/044k9ta02

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 available from the corresponding author on reasonable request. Data will become available soon after the first publication and for 5 years for public authorities and researchers who request it, explaining the reasons and uses that will be made of it, meaning that they cannot be used to be published unless otherwise authorized)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		04/12/2020	31/12/2020	No	No