

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/12/2020	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.

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 COVID-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

<http://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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

02/2020

Study information

Scientific Title

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

Acronym

MODleCOSe 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

Study design

Longitudinal observational retrospective multicenter study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

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 measure

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 ($\times 10^9$)/L
 - 6.2. Red blood cells ($\times 10^{12}$)/L
 - 6.3. Hemoglobin - HB (g/dl)
 - 6.4. Hematocrit - Hct (%)
 - 6.5. MCV (f/L)
 - 6.6. Platelets ($\times 10^9$)/L
 - 6.7. Lymphocytes ($\times 10^9$)/L
 - 6.8. Neutrophils ($\times 10^9$)/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. Albumemia (%)
 - 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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

18/12/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

>2,000

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

Sponsor details

Dipartimento PROMISE
Piazza delle Cliniche, 2
Palermo
Italy
90127
+39 91 6552250
dipartimento.promise@unipa.it

Sponsor type

University/education

Website

<https://www.unipa.it/dipartimenti/promise>

ROR

<https://ror.org/044k9ta02>

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

31/12/2021

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