ISRCTN11242213 https://doi.org/10.1186/ISRCTN11242213

The influence of obesity on COVID-19 disease

Submission date	Recruitment status	[_] Prospectively registered
03/12/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2024	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Based on the information obtained since the start of the COVID-19 pandemic, there is an urgent need to determine the impact of obesity in COVID-19 affected patients. According to several recent studies, obesity and obesity-associated illnesses such as diabetes, high blood pressure and heart disease are highly related to the development of more severe disease and a higher chance of hospitalization. The aims of this study are to determine the prevalence of obesity and its associated illnesses in hospitalized COVID-19 positive patients and to measure the increase in healthcare spending from the combination of both diseases.

Who can participate?
Patients over 18 years of age with COVID-19 during the first wave of the COVID-19 pandemic in the Community of Madrid (March to June 2020) who had to go to hospital due to their symptoms

What does the study involve?
Information is collected from patients' medical records on the prevalence of obesity and obesity-associated illnesses, the type of hospital stay, the need for invasive ventilation and ICU admission, death rates and the costs of treatments, procedures and hospitalization.

What are the possible benefits and risks of participating?
Only information collected before the start of the study is analyzed, so there are no risks of participating. Data collection and processing was carried out securely and with full data protection. The results could be beneficial to contribute to a better understanding of COVID-19 disease and the relationship with obesity and its associated illnesses, for better treatment of these patients.

Where is the study run from?
Hospital Clinico San Carlos (Spain)

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

Who is funding the study?
Novo Nordisk (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NN8022-4840

Study information

Scientific Title
The clinical and economic impact of the COVID-19 pandemic on people with obesity in Spain

Acronym
OBESITY-COVID

Study objectives
This study aims to investigate the prevalence of obesity in COVID-19 positive patients hospitalized in Hospital Clinico San Carlos (HCSC) in Madrid, Spain, from 01/03/2020 to 30/06/2020.

The secondary objectives are defined as follows:
1. To investigate the combined prevalence of obesity and obesity-associated comorbidities (diabetes mellitus [DM], hypertension [HT] and cardiovascular disease [CVD]) in COVID-19 positive patients hospitalized in HCSC in Madrid (Spain) from 01/03/2020 to 30/06/2020.
2. To describe the prevalence of obesity and the combination of obesity and obesity-associated comorbidities (DM, HT, and CVD) in COVID-19 positive patients depending on their hospital stay: visit the emergency room (EM), regular hospitalization or hospitalization at intensive care unit (ICU)
3. To describe the differences in the need for hospitalization, need for invasive ventilation, ICU admission, and mortality according to the diagnosis of obesity
4. To describe the association of obesity, obesity grade and the presence or absence of obesity-associated comorbidities with patient outcomes: need for hospitalization, need for invasive ventilation, ICU admission, and mortality according to the diagnosis of obesity
5. To evaluate the costs associated with the presence or absence of obesity, obesity grades and associated comorbidities in the treatment, procedures and hospital stay of COVID-19 patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/08/2020, Clinical Research Ethics Committee Hospital Clinico San Carlos (Comité de Ética de la Investigación con Medicamentos (CEIm), Servicio Farmacología Clínica 4ª planta, Ala Norte (Puerta G), Hospital Clínico San Carlos C/Profesor Martín Lagos, s/n 28040, Madrid, Spain; +34 (0)91 330 38 19; ceic.hcsc@salud.madrid.org), ref: 20/544-E

Primary study design
Observational

Study design
Single-centre national non-interventional retrospective registry study

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) (clinical diagnosis or confirmed laboratory diagnosis) and obesity (BMI >30 kg/m²)

Interventions
This study includes COVID-19 positive patients who required hospitalisation in the emergency room (EM), regular hospitalization or hospitalization in the intensive care unit (ICU).
Given the retrospective nature of the study design, data collection will be conducted in a single study visit. The visit procedures are stated below:

1. Selection criteria review
2. Demographic data (age, sex, sociodemographic characteristics)
3. Anthropometric measures (weight, height)
4. Clinical data:
4.1. Presence or absence of weight control measures: hypocaloric diet, physical activity, pharmacological treatment (orlistat, sibutramin, bupropion/naltrexone, fenproporex etc), surgical interventions (vertical sleeve gastrectomy, Roux-en-Y gastric bypass, adjustable gastric banding etc)
4.2. Personal history of DM (time since diagnosis, current pharmacological treatment, micro and macrovascular complications), Hb1Ac most recent value, HT, CVD, respiratory disease, (including chronic obstructive pulmonary disease [COPD], chronic bronchitis, emphysema, obstructive sleep apnoea [OSA], asthma, cystic fibrosis, pneumonia and lung cancer), and CKD.
5. Analytical data at COVID-19 onset: lymphocytes and neutrophils count, neutrophils /lymphocytes rate, c-reactive protein (CRP), ferritin, fibrinogen, LDH, D-dimer, AST, ALT, total cholesterol, triglycerides, and total protein/albumin for CONUT calculation.
6. Type and length of hospital stay (visit to EM, regular hospitalization or hospitalization at ICU)
7. Severity criteria: oxygen therapy (nasal cannulae, ventimask®, oxygen reservoir), non-invasive mechanical ventilation (bilevel positive airway pressure (BIPAP) or continuous positive airway pressure [CPAP]), invasive mechanical ventilation, mortality.
8. Pharmacological treatment during hospital stay (including nutritional support)
9. Microbiological diagnosis: PCR
10. Usual pharmacological treatment
11. Patient nutritional status assessment, if applicable

Anthropometric data and the presence of comorbidities were obtained from medical records registered in the data sources from Hospital Clinico San Carlos. When the information was not available in specialized care, it was collected from medical records registered in Primary Care. When the Body Mass Index (BMI) measurement was available, the data was used directly and the variable obesity was coded when BMI was equal to or greater than 30. If the BMI was not available, it was calculated from the most recent weight (kg) and height (m) data, using the formula BMI = weight (kg) ÷ height^2 (m).

Data sources and data management
This study will use a secondary data source. The data source will include all those databases used by the participating center (HCSC) to register assistance and management activities related to possible, probable, or confirmed COVID-19 patients, integrating information originating from different services and departments of the HCSC (emergency room, microbiology, nursery, hospital pharmacy, etc.). Data from primary care (Horus) will be included when needed. The information present in data sources must contain all data needed to calculate the study variables.
All data collected will be dumped into a data lake designed to ensure a secure and functional data location. Data will be sequentially integrated from the different data sources to the data lake, and this information will be only based on patient unique identification, date, and information characteristics.
Harmonization, standardization, and normalization of data will be needed before performing the data analysis. These processes consist of data cleaning, consistency checking, elimination of duplicities, management of odd values, variable codification to standardization (CIE10), and the creation of new variables (costs, hospital stay, etc.)
Confidentiality and data protection will be ensured in consonance with local regulations. All personal data of patients will be managed according to the adaptation of the Spanish legal system of the Regulation (EU) 2016/679 of the European Parliament and Spanish Organic Law 3 /2018, of 5th December, on Personal Data Protection and Guarantee of Digital Rights. All data

will be included in an investigational file, whose responsibility will lie with the Executive Management of HCSC, and they will be solely managed by the personnel involved in the study. As an additional confidentiality criterion, all personal data will be segregated into a separate file, and study variables will be associated with a unique coded identifier for each patient. Any date that could possibly identify the patient must be transformed (date of birth, date of hospital admission, date of surgical intervention, etc) into calculated fields (age, hospital stay, etc.). In the case of small groups, these data will be clustered to dismiss any possibility of reidentification.

Intervention Type
Other

Primary outcome(s)
Percentage of patients with obesity (BMI ≥30 kg/m²) obtained from medical records of COVID-19 positive patients hospitalized in HCSC in Madrid (Spain) from 01/03/2020 to 30/06/2020

Key secondary outcome(s)
Obtained from medical records of COVID-19 positive patients hospitalized in HCSC in Madrid (Spain) from 01/03/2020 to 30/06/2020:
1. Percentage of patients with obesity (BMI ≥30 kg/m²) and at least one obesity-associated comorbidity (DM, HTA, and CVD*)
*Cardiovascular diseases (CVD): coronary heart disease, stroke, hypertensive heart disease, inflammatory heart disease, rheumatic heart disease, TIA, and other cardiovascular diseases such as tumours, cardiomyopathy, and heart valve diseases
2. Percentage of patients with obesity (BMI ≥30 kg/m²), or obesity and at least one of the associated comorbidities (DM, HT, and CVD) per type of hospitalization: emergency room (EM), regular hospitalization or hospitalization at intensive care unit (ICU)
3. Percentage of patients in each group (BMI ≥30 kg/m² and BMI <30 kg/m²) by patient outcome: need for hospitalization, need for invasive ventilation, need for ICU admission, and mortality.
4. Percentage of obesity (BMI ≥30 kg/m²) and percentage of associated comorbidities (DM, HT and CVD) per different patient outcome. Obesity will be stratified in three different grades: grade 1: BMI ≥30-34.9 kg/m²; grade 2: BMI ≥35-39.9 kg/m² and grade 3: BMI ≥40 kg/m²
5. Mean cost of treatments, procedures and hospitalization per patient

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Patients admitted to the HCSC in hospitalization regimen (primary care health care not included) between 01/03/2020-30/06/2020 with main and/or secondary diagnosis (ICD-10 codes): U07.1, U07.2, B34.2, B97.2, J12.81, J12.89, J12.90, J18.8, J18.9 or B97.29 + [J12.89, J12, J22, J40, J80, J98.8] and registered in the BDCLIN_HCSC_COVID-19 database
2. Patients with COVID-19 microbiological diagnosis (positive PCR) and registered in the BDCLIN_HCSC_COVID-19 database from 01/03/2020 to 30/06/2020

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
5307

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2020

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínico San Carlos
Madrid
Spain
28040

Sponsor information

Organisation
Novo Nordisk Pharma S.A.

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk

Alternative Name(s)
Novo Nordisk Global

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/05/2023	04/01/2024	Yes	No