Effect of drug consumption before and during the SARS-COV-2 infection on the evolution of patients with COVID-19. A population-based study (COVIDrug)

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Study Ongoing

Administrative details

EU PAS number

EUPAS44587

Study ID

44588

DARWIN EU® study

No

Study countries

Spain

Study description

This project aims to generate knowledge from a population-based cohort study to improve the scientific evidence about susceptibility to infection by SARS-COV-2 and the severity of COVID-19 associated with different therapeutic groups. A population-based retrospective cohort study (Autonomous Community of Galicia) will be carried out, which will involve the 2.5 million subjects covered by the Galician Public Health System. A nested case-control study will be designed in this population-based retrospective cohort. All patients diagnosed with COVID-19 in the C.A. of Galicia during the study period will be considered as cases. Two groups will be used as controls, a sample from the rest of the cohort (objective G1.A) and the COVID + patients by PCR not admitted (objective G1.B). We will consider: i) exposure variables all drugs prescribed to cases and controls in the cohort, during the study period, ii) effect variables the case or control condition, iii) covariates: Age, sex, comorbidities (diabetes mellitus, obesity, history of active neoplasms, chronic obstructive pulmonary disease (COPD), asthma, hypertension, ischemic heart disease) identified through ICD-10 codes for subjects admitted to hospital and Classification International Primary Care (CIAP) in the rest. To assess the exposure to the drug or therapeutic group under study (ARBs, ACE inhibitors, NSAIDs…) we will assess the consumption of these drugs in the 6 months before the index day. Multilevel logistic regression analysis will be performed, considering each stratum (a case and the controls with the matching variables) as an aggregation unit to estimate the odds ratio, and its 95% confidence interval (CI) for the risk of Covid- 19 associated with exposures of interest.

Study status

Ongoing

Research institutions and networks

Institutions

Health Research Institute of Santiago de Compostela (IDIS)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Adolfo Figueiras

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/09/2020

Study start date

Actual: 01/10/2020

Data analysis start date
Actual: 01/09/2021

Date of final study report
Planned: 30/12/2022

Sources of funding

- Other

More details on funding

Instituto de Salud Carlos III

Study protocol

COVIDrug protocol.pdf (221.65 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

Assess whether prior consumption of certain medications (ACEIs, ARBs, ibuprofen…) conditions a greater susceptibility to infection by SARS-COV-2

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(C09A) ACE INHIBITORS, PLAIN

ACE INHIBITORS, PLAIN

(C09C) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

(M01A) ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Medical condition to be studied

Hospitalisation

Nosocomial infection

Additional medical condition(s)

ICU admision,Mortality

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

75.000

Study design details

Outcomes

Hospitalization by COVID-19

Data analysis plan

Multilevel logistic regression analysis will be performed, considering each stratum (a case and the controls with the matching variables) as an aggregation unit to estimate the odds ratio, and its 95% confidence interval (CI) for the risk of Covid- 19 associated with exposures of interest. Adjustments will be made for the above-reported covariates. Odds ratio trends will be tested,

when feasible, according to the statistical significance of the regression coefficient of the recoded variable obtained by scoring the corresponding categories. Crude and adjusted estimates will be obtained for the effect of different therapies dispensed compared with the absence of any drug therapy.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No