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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### 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**

Adolfo Figueiras adolfo.figueiras@usc.es

Study contact

adolfo.figueiras@usc.es

#### **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

#### 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**

75000

### 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

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### 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 stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No