# 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)

**First published:** 07/12/2021

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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.

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**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Health Research Institute of Santiago de Compostela (IDIS)

**First published:** 01/02/2024

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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

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**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

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**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**

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

## 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