

# ASSOCIATION BETWEEN THE USE OF DRUGS IN CHRONIC PAIN AND THE INCIDENCE AND SEVERITY OF COVID-19 INFECTION: A CASE-POPULATION STUDY (DC-COVID19)

**First published:** 07/04/2020

**Last updated:** 07/04/2020

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS34604

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### Study ID

34605

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### DARWIN EU® study

No

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### Study countries

 Spain

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## Study description

To assess if analgesic treatments and chronic pain have any impact on the prevalence and severity of COVID-19 infection through collecting population data from patients with confirmed COVID-19 with different evolution: admission requirement with only oxygen therapy support, admitted or emergency department with non-invasive ventilation requirement, admitted to Critical Unit with mechanical ventilatory support (supine, prone and ECMO) versus a control group of patients with chronic pain without COVID-19

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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Bellvitge University Hospital

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

**Last updated:** 01/02/2024

Institution

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

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

**Last updated:** 01/02/2024

Institution

## Hospital General Universitario de Alicante (ISABIAL)

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

**Last updated:** 01/02/2024

Institution

Hospital Universitari de Bellvitge L'Hospitalet de Llobregat, Barcelona (Spain), Hospital U. La Princesa Madrid (Spain), Complejo Hospitalario de Toledo Toledo (Spain), Hospital Comarcal L'Alt Penedes Barcelona (Spain), Hospital U y Politécnico La Fe de Valencia Valencia (Spain), Hospital Clínico Universitario Rio Ortega Valladolid (Spain), Hospital Clínico de Santiago de Compostela Santiago de Compostela (Spain), Hospital universitario de Ourense Ourense (Spain), Hospital General Universitario Santa Lucía Murcia (Spain), Hospital General U de Alicante Alicante

(Spain)

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Victor Mayoral

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 03/04/2020

Actual: 03/04/2020

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### Study start date

Planned: 03/04/2020

Actual: 03/04/2020

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### Data analysis start date

Planned: 04/05/2020

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### Date of interim report, if expected

Planned: 15/05/2020

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### **Date of final study report**

Planned: 29/05/2020

## Sources of funding

- Other

## More details on funding

own funds

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **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:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess if analgesic treatments and chronic pain have any impact on the prevalence and severity of COVID-19 infection through collecting population data from patients with confirmed COVID-19 with different evolution.

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Medical condition to be studied**

Coronavirus test positive

## 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)
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### **Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

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### **Estimated number of subjects**

500

## Study design details

### **Outcomes**

- To assess the association between the use of drugs and the COVID-19 infection.- To assess the association between the use of drugs and the COVID-19 infection related to the patient evolution.

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### **Data analysis plan**

500/5000Univariate: The proportion of patients on NSAIDs, corticosteroids, opioids, anticonvulsants, antidepressants, lidocaine, cannabinoids (together and separately) before the date of admission (index date) will be calculated and compared with population exposure to these drugs in a random sample of controls from databases of the Pain Units (last 6 months) and paired with the cases by age (exact), sex, Autonomous Community and month of the year. The crude OR and its 95% CI will be calculated for the association between the use of these drugs and the four outcome variables mentioned (admission by COVID-19, admission to the ICU by COVID-19, death by COVID-19 and a combined variable of the three).Multivariate: For each of the outcome variables, a conditioned logistic regression model will be constructed and the adjusted OR

for comorbidities and other treatments that the patient would have taken will be estimated.

## 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)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection, Clinical history

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No