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

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Study Ongoing

Administrative details

EU PAS number

EUPAS34604

Study ID

34605

DARWIN EU® study

No

Study countries

☐ Spain

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

Study status

Ongoing

Research institutions and networks

Institutions

Bellvitge University Hospital

First published: 01/02/2024

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Institution

Health Research Institute of Santiago de Compostela (IDIS)

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Institution

Hospital General Universitario de Alicante (ISABIAL)

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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

Study start date

Planned: 03/04/2020

Actual: 03/04/2020

Data analysis start date

Planned: 04/05/2020

Date of interim report, if expected

Planned: 15/05/2020

Date of final study report
Planned: 29/05/2020

Sources of funding

- Other

More details on funding

own founds

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:

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

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.

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

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No