CASE AND CONTROLS NESTED IN AN AMBISPECTIVE COHORT TO EVALUATE THE EFFECT OF CO-MEDICATION ON THE EVOLUTION OF SARS-CoV-2 CORONAVIRUS INFECTION (COVID-19) (HULP-COVID19-ACE2-20)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36645

EU PAS number

EUPAS34331

Study ID

36645

DARWIN EU® study

No

Study countries

☐ Spain

Study description

There is evidence that SARS-CoV-2 binds to the cellular ACE2 receptor to inoculate itself, which calls into question the use of drugs that may have an impact on the renin-angiotensin-aldosterone axis by increasing the probability of acquiring the infection. Most of the works maintain that it can favor the virus entering the body, although there is much controversy with the withdrawal or maintenance of drugs that intervene or collaterally affect this axis, since there are authors who argue that SARS-CoV -1 down-regulates ACE2 and increasingly ACE, and this can damage lung tissue, favoring the appearance of SARS. This can carry over to SARS-CoV-2 because of its genetic similarity to the former. Therefore, it is necessary to know whether withdrawal or maintenance or certain medication or vaccines are risk factors or increase the probability of a good evolution. For this last reason, we propose the present study.

Study status

Planned

Research institutions and networks

Institutions

Hospital La Paz

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Institution

School of Medicine

H. UL la Princesa Madrid, Spain

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/03/2020

Study start date
Planned: 23/03/2020

Data analysis start date
Planned: 30/06/2020

Date of interim report, if expected
Planned: 31/07/2020

Date of final study report
Planned: 31/08/2020

Sources of funding

- Other

More details on funding

Own funding

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

Disease epidemiology

Main study objective:

(i) To assess the association of previous/concomitant use of drugs or vaccines with the evolution of COVID-19.(ii) To assess the factors associated with the evolution of COVID-19 in a universal cohort of patients cared for in the hospitals

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A01AD08) becaplermin

becaplermin

(S03CA01) dexamethasone and antiinfectives

dexamethasone and antiinfectives

Medical condition to be studied

Coronavirus infection

Population studied

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Pregnant women

Estimated number of subjects

3500

Study design details

Outcomes

• Combined variable that includes:- Death- Severe pneumonia (at least one criterion from each group): Fever, or Suspected respiratory infection and respiratory rate of ≥30, or SaO2 ambient air <93%- Need to be admitted to the Intensive Care Unit- Need for mechanical ventilation- Need for FiO2 above 40%- Criteria for respiratory distress, (i)To establish what other chronic treatments are factors associated with the evolution of COVID-19.(ii) To establish which

hospital treatments are factors associated with the evolution of COVID-19.(iii) To establish what previous diseases and clinical characteristics are associated with the evolution of COVID-19.(iv)Establish that analytical values are factors associated with the evolution of COV

Data analysis plan

Having overcome the primary and secondary objectives, we proposed to be able to model some of the clinically and statistically relevant variables in order to make predictions of outcome variables, such as survival or prognosis, using propensity score ajustment.

Data management

Data sources

Data sources (types)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

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