Observational Study of Follow-up of Hospitalized Patients Diagnosed With COVID-19 to Evaluate the Effectiveness of the Drug Treatment Used to Treat This Disease. COVID-19 Registry (RegCOVID19)

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Study Planned

Administrative details

EU PAS number

EUPAS34551

Study ID

41029

DARWIN EU® study

No

Study countries

☐ Spain

Study description

The infection caused by COVID19 worldwide makes it necessary to monitor drugs administered for the treatment of patients hospitalized with SARSCoV-2. In order to know more about the efficacy and safety of the treatments used, researchers from the Cantabrian health service have developed an multi-center observational study, in the form of an ambispective registry, in which clinical data from patients treated with the different drugs currently recommended by the Spanish Agency of Medicines and Health Products (SAMHP) and the Ministry of Health, or others that may arise, are collected and analyzed. Although the conduct of clinical trials is a priority at this time, we cannot lose the clinical experience that is currently being generated, which may allow us to improve the therapeutic strategies for future patients.

Study status

Planned

Research institutions and networks

Institutions

Instituto de Investigación Sanitaria Valdecilla (IDIVAL)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

María del Mar García-Sáiz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/04/2020

Study start date

Planned: 10/04/2020

Data analysis start date

Planned: 24/04/2020

Date of interim report, if expected

Planned: 08/05/2020

Date of final study report

Planned: 30/09/2021

Sources of funding

- Other

More details on funding

Own funds

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

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Effectiveness of current drug treatments for hospitalized patients with SARS-CoV-2 infection (COVID-19 patients) in routine clinical practice, measured in terms of clinical stability, recovery and mortality.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Viral infection

Additional medical condition(s)

SARS-Cov-2 infection,COVID-19

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

1000

Study design details

Outcomes

- %Response to treatment and time to response, defined as clinical stability 3-4 days after treatment (FC<100lpm, FR<24RPM, axillary temperature<37.2ºC, SaO2>90% and adequate level of consciousness). - %Recovery and time to recovery defined as disappearance of symptoms and 2 consecutive negative PCRs at least 24 hours apart. - Mortality and time to death. - %hospitalization in the ICU. - Suspected adverse reactions to the treatments received: type, severity, prior knowledge, outcome. - Quality of life questionnaire on care received during hospitalization and after recovery.

Data analysis plan

As it is a registry, the aim is to include as many patients as possible without initially having a predetermined number. Descriptive statistics of the various variables in the record (both categorical and quantitative variables) will be carried out. In addition, provided that sufficient data is available, comparisons

will be made of the result variables according to the different treatments received by the patients using the chi-square test as well as applying multivariate analysis techniques. The Cox regression model will be used to analyse the time variables (time to response, recovery or death) and the influence of the drug treatment received and other prognostic variables.

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

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