Prospective cohort of COVID-19 cases diagnosed in Vall d'Hebron Hospital, Barcelona, during the 2020 outbreak.

First published: 31/03/2020

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS34425

Study ID

36172

DARWIN EU® study

No

Study countries

☐ Spain

Study description

A prospective cohort of patients diagnosed in the University Hopsital Vall d'Hebron, Barcelona. It is a tertiary care center with 1200 beds, acting as referral for a wide area of the Spanish territory and also as local hospital for the neighbouring quarters so the picture in our hospital is ekely to reflect all the spectrum of this new disease.In this database, the results of different treatment strategies will be also captured, allowing to provide some information about efficacy and safety (non controlled) in an outbreak setting.

Study status

Ongoing

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Adrián Sánchez-Montalvá

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/03/2020

Actual: 20/03/2020

Study start date
Planned: 31/03/2020

Actual: 31/03/2020

Date of final study report
Planned: 01/06/2020

Sources of funding

- Other

More details on funding

Non financed project

Study protocol

COVID-19_HVH_prospective.pdf(682.1 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

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe the patient outcomes at one month after symptom onset.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HYDROXYCHLOROQUINE SULFATE

LOPINAVIR

RITONAVIR

TOCILIZUMAB

DARUNAVIR

AZITHROMYCIN

INTERFERON BETA-1B

Medical condition to be studied

Pneumonia

Additional medical condition(s)

COVID-19 evaluation

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

Pregnant women

Estimated number of subjects

2300

Study design details

Outcomes

The primary outcome is the proportion of patients alive and without oxygen supply at 1 month after symptom onset. -The proportion of patients alive and without oxygen at hospital discharge, two months, 6 months and 1 year after symptom onset.-Specific secondary outcomes: Acute Respiratory Distress Syndrome, Respiratory Insufficiency and its grade, Cardiac Insufficiency, acute myocardial injury, Septic Shock, Acute Kidney Injury and secondary infections.-Patients who suffer grade 3 or superior AE

Data analysis plan

Descriptive statistics will be used for the proportions. A logistic univariate regression will be used to identify the candidate variables to enter in a multivariate logistic regression model to establish significant associations with the variables. Mortality and efficacy outcomes will be analyzed using Kaplan-Meier survival curves and Cox regression (analysis of factors associated with clinical outcomes). A propensity score test will be used to analyze the influence of the treatment regimens in clinical outcomes. A two tails p-value of 0.05 will be considered as the significance value. We have not planned an intermediate analysis. The data will be validated externally y comparing them with those

from other hospitals who have been invited to share a similar protocol.

Documents

Study publications

Sánchez-Montalvá A, Sellarés-Nadal J, Espinosa-Pereiro J, Fernández-Hidalgo N, ...

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)

Disease registry

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