SARS-CoV-2 viral load in the respiratory tract and in blood as factor associated to the clinical outcomes in adults with COVID-19 (COVID_CV)

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Study Planned

Administrative details

EU PAS number

EUPAS34443

Study ID

34579

DARWIN EU® study

No

Study countries

Spain

Study status

Planned

Research institutions and networks

Institutions

Hospital Universitario Virgen del Rocío

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Institution

Networks

REIPI

Contact details

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Primary lead investigator

Javier Sánchez Céspedes

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/04/2020

Study start date
Planned: 06/04/2020

Date of final study report
Planned: 06/04/2021

Sources of funding

- Other

More details on funding

REIPI, ISCIII

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:

To analyze the influence of the SARS-CoV-2 viral load in the lower respiratory tract (sputum, or invasive samples if clinically indicated), as well as in blood and feces (indicators of disseminated disease), as factors associated with the evolution of the disease, measured by the need for assisted ventilation and cure or death.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pneumonia

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

400

Study design details

Outcomes

Virologic variables will be included in an analysis together with demographics, co-morbidities, and the clinical and radiological characteristics of the pneumonia. Also, the sensitivity of the SARS-CoV-2 RT-PCR in nasopharyngeal swabs will be evaluated vs. sputum and viremia. Finally, the excretion and infectivity of the virus in feces will be determined after the patients are discharged, - Characterize viral load in: lower respiratory tract/blood/feces in COVID-19 pneumonia. - Analyze the association of viral load/presence of disseminated disease with the progression of pneumonia to respiratory failure and mortality. - Determine the diagnostic sensitivity of nasopharyngeal swabs vs. sputum and the excretion time in stool- Analyze the viability of the excreted virus in feces

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Data analysis plan

The inclusion of 400 patients diagnosed with COVID-19, their clinical evaluation and the virologic characterization of the infection in the proposed samples will provide us with information of key importance for the management of these patients. It will provide us with information on the optimal clinical sample to be used for greater sensitivity and specificity in the diagnosis of these patients. In addition, the evaluation of the viral load at each stage of the disease will allow us to stratify the cases based on their prognosis. The analysis of the excretion of the particles and their viability will be key when establishing adequate measures to minimize the transmission of the disease.

Data management

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