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 status** 

Planned



# Administrative details

EU PAS number	
EUPAS34443	
Study ID	
34579	
DARWIN EU® study	
No	
Study countries	
Spain	

Research institutions and networks

## **Institutions**

## Hospital Universitario Virgen del Rocío

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Institution

## **Networks**

**REIPI** 

## Contact details

### **Study institution contact**

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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)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- 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

#### **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

## **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