# Study of a prospective cohort of health professionals with coronavirus infection (COVID-19) treated with hydroxychloroquine (VDH-HID-2020-02)

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## Administrative details

EU PAS number		
EUPAS34570		
Study ID		
34571		
DARWIN EU® study		
No		
Study countries		
Spain		

**Study description** 

Prospective, non-randomized, single-centered and controlled study that evaluates whether treatment with hydroxychloroquine in COVID-19 infected health personnel (PCRpositive) reduces the time of PCR negativization and therefore the contagiousness of the disease and the duration of symptoms.

#### **Study status**

Planned

## Research institutions and networks

## Institutions



## Contact details

## **Study institution contact**

Esteve Ribera eribera@vhebron.net

Study contact

eribera@vhebron.net

**Primary lead investigator** 

## Esteve Ribera

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 31/03/2020

#### Study start date

Planned: 01/04/2020

#### Data analysis start date

Planned: 30/04/2020

#### **Date of final study report**

Planned: 27/05/2020

# Sources of funding

Other

## More details on funding

Institut Catala de Salut (ICS)

# Regulatory

Was the study required by a regulatory body?

#### 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 Effectiveness study (incl. comparative)

#### Main study objective:

To evaluate whether treatment with hydroxychloroquine in COVID-19 infected health personnel (PCR positive) reduces the time of PCR negativization and therefore the contagiousness of the disease and the duration of symptoms.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(P01BA02) hydroxychloroquine hydroxychloroquine

#### Medical condition to be studied

Coronavirus test positive

# Population studied

#### Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)</li>

#### **Estimated number of subjects**

185

# Study design details

#### **Outcomes**

To evaluate whether treatment with hydroxychloroquine in COVID-19 infected health personnel (PCR positive) reduces the time of PCR negativization and therefore the contagiousness of the disease and the duration of symptoms. Describe demographic characteristics, underlying pathologies, contraindications of hydroxychloroquine, symptoms and complications and adverse reactions to the treatment in the population study. Analyze the evolution os symptoms and whether the infection is influenced by the hospital's work areas and/or the type of care task they perform.

#### Data analysis plan

For the analysis of the primary outcome we will use the proportion of patients in thethat the PCR is negative at 7 and 10 days, which will be calculated with the intervals of 95% confidence. The analysis of the remaining the categorical variables will be expressed in frequencies and proportions. Numerical variables in means  $\pm$  standard deviation (SD) or medians and range interquartile (RI). We will consider the statistically significant value of p  $\leq$  0.05. Statistical analysis is will be carried out through the statistical program SAS® 9.4 (SAS Institute Inc. Cary, NC, USA).

# 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