

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

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Study

Planned

## Administrative details

### EU PAS number

EUPAS34570

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### Study ID

34571

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### DARWIN EU® study

No

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### Study countries

☐ Spain

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## 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.

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## Study status

Planned

# Research institutions and networks

## Institutions

University Hospital Vall d'Hebron (HUVH)

☐ Spain

**First published:** 01/02/2024

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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

Esteve Ribera

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 31/03/2020

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### **Study start date**

Planned: 01/04/2020

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### **Data analysis start date**

Planned: 30/04/2020

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### **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?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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

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**Medical condition to be studied**

Coronavirus test positive

## Population studied

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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**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 of symptoms and whether the infection is influenced by the hospital's work areas and/or the type of care task they perform.

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## Data analysis plan

For the analysis of the primary outcome we will use the proportion of patients in that 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](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No