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

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

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

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?

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

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)

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 of95% confidence. The analysis of the remaining the categorical variables will be expressed in frequencies and proportions. Numerical variables in means ± 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