# Hidroxicloroquine and cloroquine safety profile in patients with SARS-COV-2 infection (COVID-19) (SEHISACoV-2)

**First published:** 02/06/2020

**Last updated:** 15/09/2021

Study Planned

## Administrative details

**EU PAS number**

EUPAS35528

**Study ID**

40461

**DARWIN EU® study**

No

**Study countries**

☐ Spain

**Study description**

Hydroxychloroquine and chloroquine are used to treat patients with COVID19 infection. However, several trials are ongoing and there is a lack of evidence related to the efficacy yet. For years, hydroxychloroquine and chloroquine have been used to treat malaria and they are considered clinically safe. Their adverse reactions usually are mild and transitory, but both have been associated with potentially lethal cardiovascular disorders. The safety profile in patients treated with other drugs for COVID19 infection and with other comorbidities or risk factors are worst known. The primary objective is to determine the frequency of cardiovascular disorders in patients with COVID19 infection treated with CQ/HCQ and with previous risk factors. The main study variables are QT segment length (difference before-after treatment), other ECG alterations, serious adverse events as defined by ICH and grade 3/4 adverse events as classified by CTCAE v.5.

**Study status**

Planned

## Research institutions and networks

## Institutions

### Parc de Salut Mar Barcelona (PSMAR)

Spain

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

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**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**

Ana Aldea - Perona

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 27/04/2020

**Study start date**

Planned: 01/04/2020

**Data analysis start date**

Planned: 22/04/2020

**Date of interim report, if expected**

Planned: 30/06/2020

**Date of final study report**

Planned: 30/04/2021

# Sources of funding

- Other

## More details on funding

Own Funds

## Regulatory

**Was the study required by a regulatory body?**

Yes

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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:**

Other

**If ‘other’, further details on the scope of the study**

Observational safety study

**Main study objective:**

To determine the frequency of heart alterations in patients with risk factors and who receive hydroxychloroquine or chloroquine.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

COVID-19 treatment

SARS-CoV-2 test positive

Viral infection

## 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)

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**Estimated number of subjects**

158

## Study design details

**Outcomes**

QT segment length (difference before-after treatment), other ECG alterations, serious adverse events as defined by ICH and grade 3/4 adverse events as classified by CTCAE v.5.

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**Data analysis plan**

The different types of adverse events related to the study medication will be described in terms of frequency table. For the nomenclature of the adverse events, the Dictionary of adverse events' terminology MEdRA will be used and the classification by grades will follow the criteria of Common Terminology Criteria for Adverse Events (CTCAE) v5.0, published in November 2017. The relative risk will be calculated for cardiac disorders and for the rest of adverse events. The latency period and period from the start of the medication until the appearance of the first symptoms or signs of the adverse reaction will be analyzed. Each event will be expressed as median days and interquartile range. The rest of the qualitative variables will be analyzed by contingency tables and tests of Pearson's chi square test or Fisher's exact test. An intermediate analysis will be performed upon reaching 50% of the recruited sample

# Documents

**Study publications**

Chatre, C., Roubille, F., Vernhet, H. et al. Cardiac Complications Attributed t…

Cortegiani A, Ingoglia G, Ippolito M, Giarratano A, Einav S. A systematic revie…

White NJ. Cardiotoxicity of antimalarial drugs. The Lancet infectious diseases…

Haeusler, I.L., Chan, X.H.S., Guérin, P.J. et al. The arrhythmogenic cardiotoxi…

Tönnesmann E, Kandolf R, Lewalter T. Chloroquine cardiomyopathy–a review of the…

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# 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)**

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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