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

First published: 02/06/2020

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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

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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

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:

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)

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.

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…

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