Assessment of the prophylactic effect of chloroquine/hydroxychloroquine on the COVID-19 hospitalization and mortality risk in patients with rheumatic diseases: a large-scale Italian nested case-control study (ITA-COVID: HYDROXYCHLOROQUINE)

First published: 23/11/2020

Last updated: 23/11/2020

Study Finalised

Administrative details

EU PAS number

EUPAS38235

Study ID

38236

DARWIN EU® study

No

Study countries

Italy

Study description

This observational study will use Italian claims databases from 5 catchment areas (Lombardy, Veneto, Toscana and Lazio Regions as well as Reggio Emilia Local Health Unit) linked to COVID-19 patient registries in the same catchment areas. The aim of the present study will be to investigate the risk of hospitalization due to COVID-19 and the risk of intensive care unit admission and COVID-19 mortality in patients with rheumatic diseases treated with HCQ/CLQ as compared to other conventional DMARDs (cDMARDs). Secondary objective of this study will be to explore the risk of COVID-19-related hospitalization that is associated to recent use of HCQ/CLQ for rheumatic disease vs. non-use.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacoepidemiology Unit - National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità (ISS)

Italy

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Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stefania Spila Alegiani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2020

Actual: 31/03/2020

Study start date

Planned: 15/04/2020

Actual: 15/04/2020

Date of final study report

Planned: 23/12/2020

Actual: 23/11/2020

Sources of funding

- Other

More details on funding

Self-funded

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To investigate the risk of hospitalization due to COVID-19 and the risk of intensive care unit admission and COVID-19 mortality in patients with rheumatic diseases treated with HCQ/CLQ as compared to other cMARDs. To explore whether the risk of COVID-19-related hospitalization that is associated to recent use of HCQ/CLQ for rheumatic disease vs. non-use.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(P01BA02) hydroxychloroquine

hydroxychloroquine

(P01BA01) chloroquine

chloroquine

Population studied

Short description of the study population

patients with rheumatic diseases treated with chloroquine/hydroxychloroquine (HCQ/CLQ).

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)

Special population of interest

Immunocompromised

Estimated number of subjects

21000000

Study design details

Outcomes

Hospitalization due to COVID-19, risk of intensive care unit admission and COVID-19 mortality, To explore whether the risk of COVID-19-related

hospitalization that is associated to recent use of HCQ/CLQ for rheumatic disease vs. non-use

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Data analysis plan

Data will be described using frequencies, percentage, mean with standard deviations (or median with interquartile range, where appropriate). The association between chloroquine/hydroxychloroquine and/or other cDMARDs and the study outcomes will be analyzed.

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)

Administrative healthcare records (e.g., claims)

Disease registry

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