

# 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

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### Study ID

38236

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### DARWIN EU® study

No

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### Study countries

Italy

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### **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.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

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

Italy

**First published:** 23/03/2010

**Last updated:** 18/09/2023

**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

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### Study start date

Planned: 15/04/2020

Actual: 15/04/2020

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### **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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).

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### **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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### **Special population of interest**

Immunocompromised

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### **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

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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