

# IMPACT OF COLCHICINE ON PREVENTING HOSPITAL ADMISSIONS BY COVID-19: the COLCHI-COVID19 study.

**First published:** 19/04/2020

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS34810

---

### Study ID

40430

---

### DARWIN EU® study

No

---

### Study countries

☐ Spain

---

## Study description

**OBJECTIVE:** To evaluate whether the ongoing use of colchicine might, in case of SARS-CoV-2 contagion, reduce the risk of hospital admission by COVID19.

**METHODOLOGY:** 1. Design: observational, cross-sectional, analytical study. 2.

Study subjects: 2.1. Population: registered inhabitants in the Valencian region (dated April 15, 2020), and with access to the public health system. 2.2.

Inclusion criteria: A. Age  $\geq 18$  years. B. At least one attendance in the last 2 years in Rheumatology of Valencian public hospitals. C. Registered diagnoses (ICD-10 coding): - GOUT (M10.X) - CALCIUM PYROPHOSPHATE CRYSTAL

ARTHRITIS (M11.X) - FAMILIAL MEDITERRANEAN FEVER (M04.X) - BEHÇET

DISEASE (M35.2) 2.3 Exclusion criteria: none. 2.4. Sample size: The Valencian

region, with a population in 2019 of 4974969 inhabitants (INE, 2019), had at

April 3, 2020 (M. Health, update nº 64) 2064 hospitalized by COVID19. We

estimate that, in the region, there are about 8000 active prescriptions of colchicine. The sample size will likely be sufficient to observe a possible effect of colchicine on hospital admissions for COVID19. 3. Study variables: 3.1.

Outcome variables: 3.1.1. Primary: hospital admission for COVID19 3.1.2.

Secondary: intrahospital mortality from COVID19 3.2. Explanatory variables:

3.2.1. Primary: active treatment with colchicine in the study period (January to April 2020), with a prescription duration of more than 30 days. Dosing and

posology will be recorded. 3.2.2. Secondary variables: Age (in years), Sex, Type of rheumatic disease, concomitant biological therapy. 4. Data analysis:

Categorization according to the use of colchicine. In each group, the rate of hospitalization for COVID19 and intrahospital mortality will be analyzed,

estimating risks regarding the use of colchicine (odds ratio with 95%CI) by

logistic regression. Analyses will be stratified by age (quartiles), sex, type of rheumatic disease and use of biologics.

---

## Study status

Ongoing

## Research institutions and networks

## Institutions

### Hospital General Universitario de Alicante (ISABIAL)

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

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

SILVIA GOMEZ-SABATER [silviajgs@yahoo.es](mailto:silviajgs@yahoo.es)

Study contact

[silviajgs@yahoo.es](mailto:silviajgs@yahoo.es)

### Primary lead investigator

MARIANO ANDRES

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 13/04/2020

---

### Study start date

Planned: 25/09/2020

Actual: 01/04/2021

---

**Data analysis start date**

Planned: 16/10/2020

Actual: 04/04/2021

---

**Date of interim report, if expected**

Planned: 13/11/2020

---

**Date of final study report**

Planned: 18/12/2020

## Sources of funding

- Other

## More details on funding

Institute of Sanitary and Biomedical Research of Alicante (ISABIAL)

## 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:**

Effectiveness study (incl. comparative)

**Main study objective:**

The current study aims to evaluate retrospectively whether the ongoing use of colchicine due to rheumatic conditions (such as gout) might, in case of SARS-CoV-2 contagion, have reduced the risk of hospital admission by COVID19 (likely by reducing the magnitude and severity of the inflammatory expression of the disease).

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

COLCHICINE

---

**Medical condition to be studied**

Gout

Chondrocalcinosis

Behcet's syndrome

Familial mediterranean fever

---

**Additional medical condition(s)**

COVID-19

## 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)

---

**Special population of interest**

Immunocompromised

---

**Estimated number of subjects**

8000

## Study design details

**Outcomes**

The active treatment with colchicine for rheumatic diseases would have reduced the rate of COVID-19 hospitalizations. The active treatment with colchicine for rheumatic diseases would have reduced the rate of COVID-19 intrahospital mortality.

---

**Data analysis plan**

- Descriptive: categorical variables that will be presented as frequencies and percentages.- Analytical: the rheumatic population will be divided into those treated and those not treated with colchicine. In each group, the rate of hospital

admission for COVID19 will be analyzed, which will allow the estimation of an odds ratio (with a 95% confidence interval) of hospital admission according to the use of colchicine, by logistic regression. The impact on intrahospital mortality from COVID19 will be analyzed similarly.- Analyses stratified by age (quartiles), sex, type of rheumatic disease and concomitant use of biological therapy has been planned.

## Data management

### Data sources

#### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Drug dispensing/prescription data](#)

### 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