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

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/40430

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 >=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 institution and networks

Institutions

Hospital General Universitario de Alicante (ISABIAL)
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Institution

Contact details

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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 data (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