

# EFFECTIVENESS AND SAFETY OF CORTICOSTEROIDS IN SARS-COV-2 INFECTION (COVID-19): COHORT STUDY (CORTICOV-19)

**First published:** 15/04/2020

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS34753

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### Study ID

37209

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### DARWIN EU® study

No

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### Study countries

Spain

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### Study description

This is a retrospective cohort post-authorization drug study. From the patients admitted to the hospital for COVID-19 with a diagnosis of interstitial pneumonia, two cohorts will be selected based on their exposure (or not) to treatment with corticosteroids. The study will be carried out under real healthcare conditions, Data will be collected from days 1, 3 and 7 post inclusion (or treatment)

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## Study status

Finalised

## Research institutions and networks

### Institutions

Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital (HUPHM)

Spain

**First published:** 26/12/2012

**Last updated:** 20/08/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

## Contact details

### Study institution contact

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**Study contact**

[bruiz.hpth@salud.madrid.org](mailto:bruiz.hpth@salud.madrid.org)

## Primary lead investigator

Belen Ruiz-Antoran

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 13/04/2020

Actual: 13/04/2020

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### Study start date

Planned: 14/04/2020

Actual: 14/04/2020

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### Data analysis start date

Planned: 24/04/2020

Actual: 27/04/2020

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### Date of interim report, if expected

Planned: 30/04/2020

Actual: 04/05/2020

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### Date of final study report

Planned: 15/05/2020

Actual: 08/05/2020

## Sources of funding

- Other

## More details on funding

Own funds

## Study protocol

[PROTOCOLO V1.0 EFECTIVIDAD Y SEGURIDAD DE LOS CORTICOIDES EN LA INFECCIÓN POR SARS.pdf](#) (744.73 KB)

[PROTOCOLO V2.0 EFECTIVIDAD Y SEGURIDAD DE LOS CORTICOIDES EN LA INFECCIÓN POR SARS.pdf](#) (745 KB)

## 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

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the effectiveness and safety of the use of corticosteroids in the treatment of interstitial pneumonia due to COVID19 in the hospital ward to prevent the need for mechanical ventilation, ICU admission, or death.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(H02AB04) methylprednisolone

methylprednisolone

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### **Medical condition to be studied**

Coronavirus test positive

Pneumonia

## **Population studied**

### **Short description of the study population**

Adult patients admitted to Hospital Puerta de Hierro-Majadahonda between 4 March 2020 and 7 April 2020 with a diagnosis of COVID-19 pneumonia according to WHO interim guidance and complicated with ARDS and/or an hyperinflammatory syndrome where included. Of them, patients who received corticosteroid therapy according to clinical practice were assigned to the steroid cohort, while patients who did not were assigned to the control cohort.

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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**

Other

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### **Special population of interest, other**

COVID-19 patients

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### **Estimated number of subjects**

## Study design details

### Outcomes

% of patients presenting an event during the follow-up period. Event is defined as: progression to a score of 5, 6 or 7 on the 7-point Ordinal Scale (WHO) after admission by COVID-19. Time to event  
Mortality  
Hospitalization in ICU  
% of patients in need of oxygen therapy in each of its modalities (nasal glasses / mask / reservoir / high flow / NIMV or VM / ECMO)  
Days free of oxygen  
Hospitalization time  
Change in the analytical levels: Lymphocytes, Neutrophils, Dimer D, Act prothrombin, C-reactive protein, LDH, GOT, Ferritin, IL6

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### Data analysis plan

The incidence in exposed (cohort treated with corticosteroids) and in non-exposed (untreated cohort) will be calculated for each of the effectiveness variables. From these, the measures of association relative risk (RR), absolute risk reduction (RAR) and relative risk reduction (RRR) will be calculated for each of the variables, with their 95% CIs. Additionally, the odds ratios (OR) will be calculated. The RR adjusted for comorbidities and prognostic factors will be estimated.

## Documents

### Study publications

[Fernández-Cruz A, Ruiz-Antorán B, Muñoz-Gómez A, Sancho-López A, Mills-Sánchez ...](#)

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## 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)

[Electronic healthcare records \(EHR\)](#)

## 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