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

PURI

https://redirect.ema.europa.eu/resource/37209

EU PAS number

EUPAS34753

Study ID

37209

DARWIN EU® study

No

Study countries

Spain

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)

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

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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

Study start date

Planned: 14/04/2020

Actual: 14/04/2020

Data analysis start date

Planned: 24/04/2020

Actual: 27/04/2020

Date of interim report, if expected

Planned: 30/04/2020

Actual: 04/05/2020

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

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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

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.

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

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

463

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 Ordinale Scale (WHO) after admission by COVID-19. Time to eventMortalityHospitalization 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 oxygenHospitalization timeChange in the analytical levels: Lymphocytes, Neutrophils, Dimero D, Act prothrombin, C-reactive protein, LDH, GOT, Ferritin, IL6

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 ...

Data management

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No