Methyl-prednisolone pulses in COVID-19 pneumonia (COV2-MIIHUC)

First published: 13/07/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS36287

Study ID

36288

DARWIN EU® study

No

Study countries

Spain

Study description

We conducted an observational study using data collected from routine care to compare the clinical course of patients with COVID-19 pneumonia receiving week 2 methyl-prednisolone pulses (week-2-MP), 125-250 mg/d for 3

consecutive days with no subsequent tapering with standard of care. Time to death and time to death or endotracheal intubation were the outcome variables. Additional clinical and therapeutic variables were used to fit multivariate Cox proportional risk models.

Study status

Finalised

Research institutions and networks

Institutions

Biocruces Bizkaia

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Guillermo Ruiz-Irastorza

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/04/2020

Actual: 24/04/2020

Study start date
Planned: 01/05/2020

Actual: 01/05/2020

Data analysis start date
Planned: 08/06/2020

Actual: 08/06/2020

Date of final study report
Planned: 10/07/2020

Actual: 10/07/2020

Sources of funding

- Other

More details on funding

Biocruces Bizkaia

Study protocol

Memoria COV2-MIIHUC-V2-27-4-2020.pdf (147.04 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Basque Country Research Ethics Committee (code EPA2020032)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To analyse the effects of methyl-prednisolone pulses during the second week on the clinical course of patients with COVID-19 pneumonia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

METHYLPREDNISOLONE

Medical condition to be studied

COVID-19 pneumonia

Population studied

Short description of the study population

Patients with COVID-19 pneumonia admitted between 1st March and 30th April 2020 to the services of Infectious Diseases and Internal Medicine of Hospital Universitario Cruces.

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 pneumonia patients

Estimated number of subjects

353

Study design details

Outcomes

Death.Death or intubation. Nosocomial infections.

Data analysis plan

Adjusted Cox proportional risk models were fitted to assess the effect of the dichotomous variable week-2-MP as the predictor of main interest. The aforementioned variables were included in the full model. Likelihood ratio tests were used in a sequential fashion in order to find a reduced adjusted model containing statistically significant covariates. Hazard ratios (HR) with 95% confidence intervals were used to estimate the magnitude of the association between risk predictors and outcomes. Proportionality of hazards was tested through the use of comparison of adjusted and predicted survival curves and

Schoenfeld residuals.

Documents

Study results

Summary of resullts.pdf (35.65 KB)

Study, other information

EPA2020032 (EPA-OD) InformeDictamenFavorableEPA.pdf (285.79 KB)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown