VILA-COVID 19 RETROSPECTIVE OBSERVATIONAL CLINICAL STUDY PROTOCOL: EARLY ADMINISTRATION OF CORTIC THERAPY AND ANTI-INFLAMMATORIES IN PATIENTS WITH COVID 19 DIAGNOSIS. (COVID-19) (VILACOVID 19-CTC)

First published: 25/04/2020

Last updated: 02/07/2020

Study Ongoing

Administrative details

EU PAS number

EUPAS34934

Study ID

36151

DARWIN EU® study

No

Study countries

Spain

Study description

n the current pandemic situation, standardization criteria are lacking in the use of corticosteroids in patients with ARDS secondary to COVID 19. The objective of our study is to record our experience in the treatment of patients with COVID 19, to assess the results of those who have corticosteroid therapy, anti-inflammatory drugs (colchicine and / or indomethacin), biological therapies (tocilizumab and / or anakinra) and immunoglobulins, quantifying the evolution of the reactants in the acute phase of these patients (PCR, ferritin, Dimero D, IL 6), the PAFI or SAFI (if PAFI not available) and radiological changes of the patient

Study status

Ongoing

Research institutions and networks

Institutions

Hospital de Viladecans-Universidad de Barcelona

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Institution

Contact details

Study institution contact

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Primary lead investigator

Ana María Ponce

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/04/2020

Actual: 16/03/2020

Study start date

Planned: 13/03/2020

Actual: 16/03/2020

Data analysis start date

Planned: 08/06/2020

Date of interim report, if expected

Planned: 01/08/2020

Date of final study report

Planned: 01/09/2020

Sources of funding

- Other

More details on funding

Hospital

Study protocol

Protocol_villacovid 19.pdf (457.84 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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

he objective of our study is to record our experience in the treatment of patients with COVID 19, to assess the results of those who have received corticosteroid therapy, anti-inflammatory drugs (colchicine and / or indomethacin), biological therapies (tocilizumab and / or anakinra) and immunoglobulins, quantifying the evolution of the acute phase reactants of these patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Respiratory failure

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- 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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

600

Study design details

Outcomes

Describe our findings in patients diagnosed with COVID 19+ who have received early corticosteroid therapy, in relation to oxygen requirements and / or need for IOT, and compare these findings with the results of patients diagnosed with COVID 19 + who have not received early corticosteroid therapy in the same period of time. Describe the optimal time of administration of early corticosteroid therapy based on the clinical, analytical, PAFI (or SAFI) and radiological characteristics Describe the time of early administration based on the age of the patient. Describe the clinical, analytical and radiological findings if tocilizumab, anakinra or Immuglobulines have been administered. Describe the days of hospitalization

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Data analysis plan

The statistical analysis will be done using spss version 22.0. It will include the following procedures: Description of the variables. We will use means and standard deviation in cases of continuous variables with normal distribution, and means with interquartile intervals for continuous variables that do not meet normality criteria. Qualitative variables will be expressed with names and percentages. Chi-square or Fisher's test statistical techniques were used to compare the qualitative variables. For the quantitative variables that meet the normality criteria, Student's T will be used, for those that do not follow the normal distribution, parametric n tests will be used (Mann-Whitney U). The differences between groups they will be carried out using linear models with the practice of ultrasound study as a grouping variable and clinical parameters as adjustment covariates.

Documents

Study publications

Mahallawi WH, Khabour OF, Zhang Q, Makhdoum HM, Suliman BA. MERS-CoV infection ...

Xu Z, Shi L, Wang Y, Zhang J, Huang L, Zhang C, Liu S, Zhao P, Liu H, Zhu L, Ta...

Shi Y, Wang Y, Shao C, Huang J, Gan J, Huang X, Bucci E, Piacentini M, Ippolito...

Mahallawi WH, Khabour OF, Zhang Q, Makhdoum HM, Suliman BA. MERS-CoV infection ...

Wong CK, Lam CW, Wu AK, Ip WK, Lee NL, Chan IH, Lit LC, Hui DS, Chan MH, Chung ...

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.

Conflicts of interest of investigators

Ana María Ponce López.pdf (26.4 KB)

Data sources

Data sources (types)

Disease registry

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