

COHORTE DE PACIENTES EN TRATAMIENTO RENAL SUSTITUTIVO HOSPITALIZADOS POR COVID-19. MORTALIDAD Y FACTORES PRONÓSTICOS (COVID19-HD)

First published: 19/04/2020

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Study

Ongoing

Administrative details

EU PAS number

EUPAS34813

Study ID

34899

DARWIN EU® study

No

Study countries

 Spain

Study description

The new SARS-CoV-2 virus pandemic started in December 2019 in Wuhan, China and has spread rapidly globally. It mainly affects the respiratory and gastrointestinal tract with a mortality that ranges between 1.4 and 8% according to published records. Prognostic factors for poor evolution include advanced age, male sex, and a history of cardiovascular disease, diabetes mellitus, chronic obstructive pulmonary disease, or cancer. The course of the disease in patients requiring renal replacement therapy is poorly understood. Given the comorbidity and advanced age of these patients, mortality could be higher than that of the general population. The main objective of this study is to describe the clinical presentation in patients on renal replacement therapy and to analyze the clinical and analytical prognostic factors in this patient population, as well as the impact of the different treatments used.

Study status

Ongoing

Research institutions and networks

Institutions

Ethics Committee of the Hospital General
Universitario Gregorio Marañón (CEIm HGUGM)

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Institution

Contact details

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Primary lead investigator

Maria Angeles Goicoechea

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2020

Actual: 19/04/2020

Study start date

Planned: 12/03/2020

Actual: 19/04/2020

Date of final study report

Planned: 30/12/2020

Sources of funding

- Other

More details on funding

no funding

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

MAIN OBJECTIVE To assess the clinical, analytical, and therapeutic prognostic factors on Covid-19 mortality in patients on renal replacement therapy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

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

Renal impaired

Estimated number of subjects

150

Study design details

Outcomes

clinical, analytical, and therapeutic prognostic factors on Covid-19 mortality in patients on renal replacement therapy, 1) Analyze the characteristics and analytical clinics of patients on a chronic hemodialysis program/kidney transplant and acute kidney failure 2) Analyze the analytical, clinical factors

associated with the prognosis of hemodialysis patients (kidney transplant and acute kidney failure³) Analyze the influence of different therapeutic schemes on the prognosis

Data analysis plan

MAIN VARIABLE: mortality
SECONDARY VARIABLES: Demographic variables: age, sex, race, body mass index, etiology of chronic kidney disease, comorbidities, type of renal replacement therapy. Clinical variables: symptoms and radiology of COVID-19 infection. Analytical variables: hemoglobin, platelets, lymphocytes, dimer-D, kidney function, liver function, inflammatory parameters: C-reactive protein, procalcitonin, ferritin, interleukin-6. Therapeutic scheme used for COVID-19 infection: lopinavir / ritonavir, azithromycin, hydroxychloroquine, corticosteroids, tocilizumab, interferon beta, or remdesivir.

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)

[Disease registry](#)

[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

No