A retrospective study to evaluate the clinical effectiveness and safety of treatments for Covid-19 hospitalised patients and to determine prognostic factors. (RAPID COVID-19)

First published: 12/05/2020

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS35254

Study ID

35991

DARWIN EU® study

No

Study countries

☐ Spain

Study description

RAPID COVID-19 (Retrospective Analysis of Potential Interventions and Determinants). This retrospective study aims to evaluate the clinical effectiveness and safety of various treatments and regimes and prognostic factors in hospitalised patients with COVID-19 in Spain.

Study status

Ongoing

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 25/05/2020

Actual: 19/05/2020

Study start date

Planned: 25/05/2020

Actual: 19/05/2020

Date of final study report

Planned: 24/02/2021

Sources of funding

- Other

More details on funding

OXON Epidemiology

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To compare in-hospital clinical status in patients with Covid-19 treated with standard care and various treatments and determine prognostic factors.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

HYDROXYCHLOROQUINE

LOPINAVIR

RITONAVIR

AZITHROMYCIN

REMDESIVIR

INTERFERON ALFA-2B

INTERFERON BETA-1A

INTERFERON BETA-1B

TOCILIZUMAB

SARILUMAB

SARS-COV-2 CONVALESCENT PLASMA

DARUNAVIR

COBICISTAT

Medical condition to be studied

COVID-19

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

2000

Study design details

Outcomes

6-point ordinal scale at 14 days:, 6-point ordinal scale at 7 and 28 days, In-hospital death at 28 days, mechanical ventilation, renal replacement therapy, duration of hospitalization, duration of ICU stay, serious complications and serious adverse eventsPrediction score

Data analysis plan

The primary analysis will use an ordered polytomous logistic regression model to assess 14 day in-hospital clinical status on a 6-point ordinal scale, with adjustments. Results will be presented as odds ratios Secondary analysis of death at 28 days will use logistic regression, also with adjustments.Multivariable ordered polytomous logistic regression will be used to determine key predictors of the primary ordinal scale outcome. Multivariable logistic regression will be used to determine key predictors of the secondary outcome of death at 28 days, mechanical ventilation and renal replacement therapy. The final

predictive model will be converted into a clinician-friendly index.

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

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