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

PURI
https://redirect.ema.europa.eu/resource/35991

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 institution and networks

Institutions

OXON Epidemiology

Spain
United Kingdom
First published: 06/12/2010
Last updated
15/03/2024

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

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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Primary lead investigator

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

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