INTERNATIONAL COVID-19 CLINICAL EVALUATION REGISTRY: HOPE-COVID 19. (Health Outcome Predictive Evaluation for COVID 19) (HOPE COVID 19)

First published: 31/03/2020

Last updated: 10/06/2020

Study Ongoing

Administrative details

EU PAS number

EUPAS34399

Study ID

35740

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Canada
- ☐ China

- [ ] Ecuador
- [ ] Germany
- [ ] Italy
- [ ] Spain

Study description

PURPOSE The main objective of the present study is to carefully characterize the clinical profile of patients infected with COVID-19 in order to develop a simple prognostic clinical score allowing, in selected cases, rapid logistic decision making (discharge with follow-up, referral to provisional/field hospitals or admission to more complex hospital centers).As secondary objectives, the analysis of the risk-adjusted influence of treatments and previous comorbidities of patients infected with the disease will be performed.DESIGNCross-sectional and ambispective registry, a real life “all comers” type, with voluntaryparticipation, without funding or conflicts of interest. It is a study initiated by researcher thatwill have advanced statistical support from the IMAS foundation (Institute for the Improvementof Health Care, Madrid, Spain).International level.PATIENTS We propose to select all the patients attended in any health center (with in hospital beds), whohave been discharged or have died at the time of the evaluation.All will be considered eligible with a positive COVID 19 test (any type) or if their attendingphysicians consider them highly likely to have presented the infection.There are no exclusion criteria, except for the patient's explicit refusal to participate.

Study status

Ongoing

Research institutions and networks

Institutions

Hospital Clinico San Carlos

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ivan J. Nuñez Gil

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/03/2020

Study start date

Planned: 25/03/2020

Actual: 27/03/2020

Data analysis start date
Planned: 31/03/2020

Actual: 31/03/2020

Date of interim report, if expected
Planned: 06/04/2020

Actual: 06/04/2020

Date of final study report
Planned: 06/07/2020

Sources of funding

- Other

More details on funding

TBD

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

Main study objective:

Revie mortality factors in COVID 19

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Viral infection

Additional medical condition(s)

COVID-19

Population studied

Age groups

- 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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

2000

Study design details

Outcomes

Mortality, Clinical eventos.

Data analysis plan

Univariate and multivariate analysis. Depending on results probably propensity score assesment.

Documents

Study, other information

HOPE_STEERING_PI AND COLLABORATORS.pdf (329.27 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)

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