Real-world characteristics, management and outcomes of subjects screened or diagnosed with COVID-19 in Spain (COVID-19 REAL)

First published: 31/03/2020

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46384

EU PAS number

EUPAS34411

Study ID

46384

DARWIN EU® study

No

Study countries

Spain

Study description

The study is a non-interventional, retrospective, database, cohort study based on anonymized and routinely-collected health care data from several Spanish Hospitals which have been mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The present study aims to participate in the OHDSI international collaboration by analyzing data from Spain. Further analyses to answer specific, local COVID-19 research questions that may arise during the ongoing crisis might be also considered.

Study status

Finalised

Research institutions and networks

Institutions

TFS HealthScience (TFS)

Sweden

First published: 01/02/2024

Last updated: 03/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

University Hospital Vall d'Hebron (HUVH)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Parc de Salut Mar Barcelona (PSMAR)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Hospital Vall Hebron Barcelona (Spain), Hospital del Mar Barcelona (Spain), Hospital de Cruces Barakaldo (Spain), Hospital San Eloy Barakaldo (Spain), Hospital Urduliz Urduliz (Spain)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Neus Valveny

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2020

Actual: 14/05/2020

Study start date

Planned: 09/12/2020

Actual: 09/12/2020

Data analysis start date

Planned: 15/12/2020

Actual: 15/12/2020

Date of interim report, if expected

Planned: 01/03/2020

Actual: 01/03/2021

Date of final study report

Planned: 31/12/2021

Actual: 01/03/2022

Sources of funding

- Other

More details on funding

TFS, IOMED, Bill Gates Foundation (through Oxford University)

Study protocol

OHDSI COVID-19 Real_protocol_25Mar20.pdf(649.19 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

YOC-CLO-2020-01 (AEMPS identification number)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

Describing the characteristics of subjects screened and/or diagnosed with COVID-19 in Spain Describing therapeutic management in the clinical practice Describing clinical outcomes for the infected subjects Assessing predictor factors for infection, hospitalization,intensive care admission and death Exploring effectiveness and safety of administered therapies

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Medical condition to be studied

Pneumonia

Additional medical condition(s)

COVID-19PneumoniaViral Infection

Population studied

Age groups

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)

Estimated number of subjects

8000

Study design details

Outcomes

Sociodemographic and lifestyle Geographical/Ethnic origin History of exposure to COVID-19 and dates, test results and viral load, if available Current and past concomitant medications Current and past comorbidities Diagnosis, clinical symptoms and signs Laboratory values Severity scores, Infection status Pneumonia status Recovery status and time to recovery Hospitalization and length of stay ICU admission and length of stay Overall survival Complications during infection (bacterial pneumonia, sepsis…) Recurrence/reinfection

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Data analysis plan

Descriptive analysis in the overall sample and by subgroups of interest (e.g. Hospital, gender, age subgroups, smoking history, diabetes status, cardiovascular history etc.) Multivariable Cox Regression to estimate Hazard

ratios Multivariable Logistic Regression to estimate Odds ratios

Documents

Study publications

Reyes C, Pistillo A, Fernández-Bertolín S, Recalde M, Roel E, Puente D, Sena AG...

Kostka K, Duarte-Salles T, Prats-Uribe A, Sena AG, Pistillo A, Khalid S, Lai LY...

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Routine Hospital Electronic Medical Records

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