# 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





## Administrative details

#### **PURI**

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

#### **EU PAS number**

**EUPAS34411** 

#### Study ID

46384

#### DARWIN EU® study

No

#### Study countries

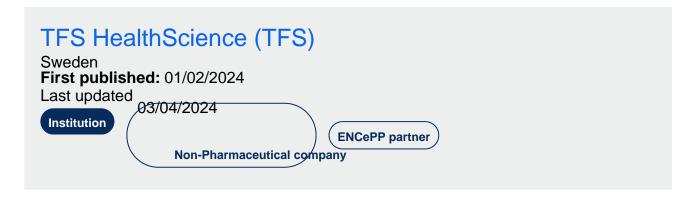
Spain

#### 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.

## Research institution and networks

## Institutions







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

**Neus Valveny** 

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 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

#### 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