Project Sc(y)lla: SARS-Cov-2 Large-scale Longitudinal Analyses on the comparative safety and effectiveness of treatments under evaluation for COVID-19 across an international observational data network

First published: 18/09/2020

Last updated: 10/03/2021

Study Planned

Administrative details

EU PAS number

EUPAS37225

Study ID

39922

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

☐ Korea, Republic of

☐ Netherlands

☐ United Kingdom

☐ United States

Study status

Planned

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

☐ Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

SIDIAP Spain, IPCI Netherlands

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

European Health Data Evidence Network (EHDEN)

☐ Netherlands

First published: 01/02/2024

Last updated: 11/06/2024

Network

Contact details

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Study contact

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Primary lead investigator
Daniel Prieto-Alhambra

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2020

Study start date
Planned: 01/01/2020

Date of final study report
Planned: 30/06/2021

Sources of funding

- Other

More details on funding

Bill and Melinda Gates Foundation, IMI EHDEN, Others

Study protocol

PLE COVID effectiveness protocol v1.2.1.pdf(1.03 MB)

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

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Specifically, the study has the following objectives:1. To assess comparative effectiveness and safety among treatments administered during hospitalization and prior to intensive services2. To assess comparative effectiveness and

safety among treatments administered after COVID-19 positive testing or diagnosis in outpatient setting without prior hospitalization

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Corticosteroids, Interleucin inhibitors, JAK inhibitors, Statins, Anti-diabetics, Protease inhibitors, Anticoagulants

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

HYDROXYCHLOROQUINE

Anatomical Therapeutic Chemical (ATC) code

(C02) ANTIHYPERTENSIVES

ANTIHYPERTENSIVES

(J02AA) Antibiotics

Antibiotics

Medical condition to be studied

COVID-19 treatment

Population studied

Age groups

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

2500000

Study design details

Data analysis plan

One study design, with multiple different analysis variants, will be conducted after appropriate diagnostics to rule out power and/or confounding issues. For each research question in section 8, we have identified treatments that 1) have in vitro antiviral activity for SARS-COV-2 virus, or 2) are considered concomitant therapies for the COVID-19 disease. The latter are subdivided into antithrombotics, antibiotics, immune-based therapies, concomitant anti-hypertensive, concomitant anti-diabetics, concomitant statin, and other concomitant treatments (see Appendix 1). For each question, we will make pairwise comparisons of all treatments within these eight categories of therapies (e.g. compare all drugs with antiviral activity against each other, and separately compare all antithrombotic therapies with each other). For each comparison, we will estimate and compare the incidences of each outcome in Appendix 2 during the time-at-risk windows defined in 9.2.3.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

CPRD, IPCI, SIDIAP

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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