Spanish Registry of treatment efficacy against SARS-CoV-2 COVID-19 (RER-FAR-COVID-19)

First published: 29/03/2020

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Study Planned

Administrative details

EU PAS number

EUPAS34343

Study ID

34344

DARWIN EU® study

No

Study countries

Spain

Study description

Evaluated the effectiveness of pharmacotherapy used in the treatment of cases of SARS-CoV2 coronavirus infection, whom have required hospital admission in Spain during the pandemic declared in March 2020.

Study status

Planned

Research institutions and networks

Institutions

Spanish Society of Hospital Pharmacy

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jesus F Sierra Sánchez

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/03/2020

Study start date
Planned: 30/03/2020

Data analysis start date
Planned: 03/04/2020

Date of interim report, if expected
Planned: 10/04/2020

Date of final study report
Planned: 29/05/2020

Sources of funding

- Other

More details on funding

Spanish Society of Hospital Pharmacy

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To Evaluate the effectiveness of pharmacotherapy used in the treatment of cases of SARS-CoV2 coronavirus infection who have required hospital admission in Spain during the pandemic declared in March 2020.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

AZITHROMYCIN

CHLOROQUINE

COBICISTAT

DARUNAVIR

EMTRICITABINE

FOSAMPRENAVIR

HYDROXYCHLOROQUINE SULFATE

INTERFERON BETA-1B

LOPINAVIR

REMDESIVIR

RITONAVIR

TENOFOVIR

TOCILIZUMAB

Medical condition to be studied

Pneumonia

Additional medical condition(s)

SARS-CoV-2 infection

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)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

10000

Study design details

Outcomes

Remission rate of the disease at 14 days (proportion, 95% CI), understanding remission as:- Improvement of symptoms (fever, cough ...) together with radiological improvement and/or- PaFi> o = 300 mm Hg or O2 saturations> 93 without O2 administration.

Data analysis plan

Accordind the exceptional situation, no sample size has been calculated to achieve the primary objective. However, intermediate analyzes will be made based on the inclusion of completed cases (discharge / exitus or 14 days of treatment) every week. The beta error of each of the treatment groups will be calculated from each analysis cut to determine if the number of patients included is powerful enough to draw conclusions. At least a beta error of 20% (power of 80%) and an alpha error of 5% will be assumed.

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

Drug dispensing/prescription data

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