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

First published: 29/03/2020
Last updated: 01/07/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/34344

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 institution and networks

Institutions

Spanish Society of Hospital Pharmacy

First published: 01/02/2024
Last updated
01/02/2024

Institution

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain
First published: 01/02/2024
Last updated
01/07/2024

Institution

EU Institution/Body/Agency

Not-for-profit

Regulatory Authority

Contact details

Study institution contact
Jesus F Sierra Sánchez

Study contact

jesusf.sierra.sspa@juntadeandalucia.es
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

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