Determination of phenotypes predicting complications in COVID-19 and evaluation of the efficacy of immunosuppressive treatments (INMUNOSUPR COVID-19)

First published: 07/04/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34607

Study ID

40909

DARWIN EU® study

No

Study countries

☐ Spain

Study description

The aim of the project is (1) to identify phenotypes that predict the need for mechanical ventilation in the initial evaluation of patients and their evolution in the first days of admission, and (2) to evaluate the efficacy and safety of immunosuppressive treatments used in patients without mechanical ventilation with elevated markers of macrophage activation syndrome. They will be carried out through multi-centre retrospective cohort studies, with advanced statistical analysis for observational studies.

Study status

Finalised

Research institutions and networks

Institutions

Hospital Universitario Virgen Macarena

Spain

First published: 01/02/2024

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

HU Juan Ramón Jiménez Huelva, HU Puerta del Mar Cádiz, HU Puerto Real Cádiz, HU de Jeréz Cádiz, HU Regional de Málaga Málaga, HU Costa

del Sol Málaga, HU Virgen de Valme Sevilla, HU San Cecilio Granada, CHU A coruña A Coruña, HU de las Cruces Vizcaya

Networks

ANCRAID

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jesús Rodríguez-Baño

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2020

Actual: 15/05/2020

Study start date
Planned: 21/05/2020

Actual: 21/05/2020

Data analysis start date
Planned: 01/06/2020

Actual: 01/06/2020

Date of interim report, if expected
Planned: 15/06/2020

Actual: 15/06/2020

Date of final study report
Planned: 01/04/2021

Actual: 01/04/2021

Sources of funding

- Other

More details on funding

ISCIII

Study protocol

Protocolo FIS-INM-2020-03_1.0_07042020_JRB_.pdf(381.92 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

Code: FIS-INM-2020-03

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

1 will serve to stratify patients in their evaluation in the ED and decide their initial more or less aggressive admission and management.2 will serve to provide the first evidence of clinical efficacy of immunosuppressive/immunomodulatory treatments in patients with a well-defined profile by the specified analytical criteria, additionally it will serve for the design of randomized trials.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Patients with COVID-19 and clinical and laboratory data indicative of a hyperinflammatory state.

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

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

800

Study design details

Data analysis plan

Analysis of treatment association with the outcome variable after propensity score calculation

Documents

Study, other information

EUPAS34607_abstract.pdf(372.38 KB)

Data management

Data sources

Data sources (types)

Disease registry

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