Multicentric Study of Coronavirus Disease 2019 (COVID-2019) in Solid Organ Transplant Recipients (COVIDSOT) (COVID-19)

First published: 30/03/2020

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/34406

EU PAS number

EUPAS34349

Study ID

34406

DARWIN EU® study

No

Study countries

☐ Italy

☐ United Kingdom

Study description

The overall purpose of this project is to better understand the incidence, risk factors, etiology, clinical manifestations and outcome of tCOVID19 in solid organ transplant recipients. The results obtained will allow us to gain insight on the need of antiviral treatment, on the strategy for complications surveillance, on how to adjust the immunosuppressant therapy and on the level of care in which each patient should be treated. In order to attain the objectives previously described we will develop a multicenter prospective study of consecutive cases of COVID-19 among solid organ transplant recipients. Length of viral shedding and immunological response will be also studied. There will be a clinical follow-up of the patients included in this study to observe possible complications and survival rate. For those centers who cannot recover biological samples, only clinical data will be included. Data collected form this study will be evaluated with a descriptive statistical analysis of the cohort consisting of a univaried analysis of the risk factors of COVID-19. Subsequently a multivaried logistic regression analysis will be performed in which the factors selected from the univaried analysis and those clinically relevant.

Study status

Ongoing

Research institutions and networks

Institutions

Hospital Universitario Virgen del Rocío

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Institution

Networks

REIPI

Contact details

Study institution contact

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Primary lead investigator

Elisa Cordero

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/03/2020

Actual: 13/03/2020

Study start date

Planned: 20/03/2020

Actual: 20/03/2020

Date of final study report

Planned: 13/03/2022

Sources of funding

- Other

More details on funding

ISCIII

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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To know the incidence, clinical manifestations and outcome of infections of COVID-19 on Solid Organ Transplant Recipients

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Solid organ transplant

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

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

50

Study design details

Outcomes

1. Incidence of coronavirus infection in Solid Organ Transplant Recipients2. Clinical manifestations of coronavirus infection in Solid Organ Transplant Recipients 3. Presence of other risk factors4. Establish the frequency and type of complications related to the net state of the patientimmunosuppression, 1. Frequency of co-infections2. Mortality3. Laboratory characteristics4. Determination of coronavirus viral load5. Microbiological testing

Data analysis plan

Results obtained during the study will be analyzed using the SPSS statistical software (version 15.0, SPSS Inc, Chicago, Illinois). A descriptive analysis of all data obtained will be performed. In order to detect significant differences between groups, a Chi-square or a Fisher exact test in the case of categorical variables and the t or a Mann-Whitney test for continuous variables will be applied. Furthermore, a linear trend analysis will also be used, in the case of multiple comparisons. In the multivariate analysis all the variable related to un

unfavorable outcome in the unvaried analyses and those, that are clinically relevant significant, will be included.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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