The prognosis of coronavirus disease (COVID-19) in patients recently treated with immunosuppressant medications.

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Study Ongoing

Administrative details

EU PAS number

EUPAS36056

Study ID

41572

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Immunosuppressant medications are effective treatments for several immune-mediated inflammatory diseases, as well as vasculitides, chronic lung diseases and certain malignancies. These medications have a strong effect on the immune system decreasing inflammation, but this has prompted concerns regarding the body’s defence against infection. This is particularly pertinent during the current epidemic of coronavirus (COVID-19), as a weakened immune system may be vulnerable to severe coronavirus disease. We aim to evaluate the prognosis of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) infection in patients treated with immunomodulating medications, including immunosuppressants and systemic glucocorticoids. We will leverage unique Danish health registers to conduct a nationwide cohort study of the outcome of SARS-COV-2 infection, i.e. admission to hospital, admission to intensive care unit (intensive care observation/intensive care therapy) or death, in this patient population, with adjustment for the severity of patients’ underlying indication for immunosuppression, as well as other factors that may affect the course of coronavirus disease.

Study status

Ongoing

Research institutions and networks

Institutions

University of Southern Denmark (SDU)

Denmark

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jesper Hallas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/02/2020

Actual: 27/02/2020

Study start date

Planned: 27/02/2020

Actual: 27/02/2020

Data analysis start date

Planned: 30/06/2020

Date of final study report
Planned: 30/07/2020

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Lundbeck Foundation, University of Southern Denmark

Study protocol

EUPAS protocol.pdf(873.33 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Main study objective:

To study the risk of severe outcomes in patients with SARS-COV-2 infection, comparing those with a recent history of exposure to immunosuppressant medications to patients without a recent history of exposure.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02AB) Glucocorticoids

Glucocorticoids

(L01XC02) rituximab

rituximab

(L04AA) Selective immunosuppressants

Selective immunosuppressants

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

(L04AC) Interleukin inhibitors

Interleukin inhibitors

(L04AD) Calcineurin inhibitors

Calcineurin inhibitors

(L04AX) Other immunosuppressants

Other immunosuppressants

(P01BA01) chloroquine

chloroquine

(P01BA02) hydroxychloroquine

hydroxychloroquine

Medical condition to be studied

SARS-CoV-2 test positive

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

Pregnant women

Renal impaired

Estimated number of subjects

12675

Study design details

Outcomes

Death registered in the Danish register of Causes of Death within 30 days following a the first positive SARS-CoV-2 test registered in the Danish Microbiology Database. Hospital admission and intensive are unit admission (each event separately) registered in the Danish National Patient Register within 30 days following a the first positive SARS-CoV-2 test.

Data analysis plan

Risk ratio estimated by log-linear binomial regression.

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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