Impact of the COVID-19 epidemic on people with an inflammatory disease (COVIMID)

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Study Ongoing

Administrative details

EU PAS number

EUPAS44456

Study ID

44457

DARWIN EU® study

No

Study countries

☐ France

Study description

The proposed study will have an important impact in our knowledge on the impact of such outbreaks in Immune-Mediated Inflammatory Diseases (IMID) patients, namely: - Assessment of the incidence of severe COVID-19 cases in

IMID patients, - Comparison of incidence of severe COVID-19 infections in IMID patients compared to the general population, - Comparison of incidence of severe COVID-19 infections in IMID patients treated with targeted Immuno-Modulating Agents (IMA) or conventional synthetic agents compared to the general population, - Assessment of a differential impact between IMA (e.g. IL-6 blockade versus other modes of action) or Anti-Retroviral Therapy (ART) (e.g. daranuvir/atazanavir/bictegravir/lopinavir versus other ARTs) on the incidence of COVID-19 infections, - Identification of the impact of COVID-19 infection of untimely drug tapering and discontinuation in IMID patients, in terms of loss of compliance as well as disease flare or related consequences. The results will fuel relevant information to set up clinical practice guidelines for the management of IMID patients and their treatments in the context of emergent outbreaks, and to enhance communication of risk.

Study status

Ongoing

Research institutions and networks

Institutions

Assistance Publique - Hôpitaux de Paris (AP-HP)

France

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Institution **Hospital/Clinic/Other health care facility**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bruno FAUTREL

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/03/2020

Actual: 03/06/2020

Study start date

Planned: 01/07/2020

Actual: 22/06/2021

Data analysis start date

Planned: 01/07/2020

Actual: 22/06/2021

Date of final study report

Planned: 31/12/2022

Sources of funding

- Other

More details on funding

French Ministry of Health

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

Drug utilisation

Main study objective:

The main objective of the study was to assess the risk of severe COVID-19 among two distinct IMID populations (IMID patients suffering from systemic or organ-specific inflammatory disorders (sosIMID) treated with IMA and IMID patients suffering from HIV (hivIMID) treated with ART, respectively), compared to the general population (individuals without IMID and not treated with IMA or ART).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AF) Nucleoside and nucleotide reverse transcriptase inhibitors

Nucleoside and nucleotide reverse transcriptase inhibitors

(J05AG) Non-nucleoside reverse transcriptase inhibitors

Non-nucleoside reverse transcriptase inhibitors

(J05AR) Antivirals for treatment of HIV infections, combinations

Antivirals for treatment of HIV infections, combinations

(J05AE) Protease inhibitors

Protease inhibitors

(J05AX) Other antivirals

Other antivirals

(L04AC) Interleukin inhibitors

Interleukin inhibitors

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

Tumor necrosis factor alpha (TNF-alpha) inhibitors

(L03AB) Interferons

Interferons

(L04AX03) methotrexate

methotrexate

(L01XC02) rituximab

rituximab

Medical condition to be studied

Multiple sclerosis

Neuromyelitis optica spectrum disorder

Vasculitis

Rheumatoid arthritis

Systemic lupus erythematosus

Crohn's disease

Spondylitis

Psoriasis

Colitis ulcerative

HIV infection

Additional medical condition(s)

Myelitis,Still’s disease,Juvenile idiopathic arthritis Psoriatic arthropathy Juvenile psoriatic arthritis Arthritis enteropathic Cutaneous lupus erythematosus,Systemic scleroderma,Polymyositis

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

Immunocompromised

Estimated number of subjects

1078000

Study design details

Outcomes

Hospital stay in ICU with a specific code of COVID-19 (as principal or related diagnosis) and/or death during a hospital stay with COVID-19 as principal or related diagnosis. A specific ICD-10 code related to COVID-19 infection (U07.1) has been implemented and a specific ICD-10 code for suspicion of COVID-19 is coming. Less severe COVID-19 infections (hospitalization for COVID-19 without ICU stay or death), Death (whatever the place of death), COVID-related deaths occurring during hospitalization with COVID-19, Spacing or discontinuation of IMA and ART dispensation, IMID flare or destabilization (hospital stay with IMID). HIV complications (hospital stay with HIV or complication related to HIV).

Data analysis plan

The percentage of severe COVID-19 infections will be compared between IMID patients treated with IMA on the one hand and the HIV population treated with ART on the other hand, taking into account the matching on sex and age with controls from the general population, and using a logistic regression model with inverse probability of treatment weighting (IPTW) propensity score. One

propensity score will be performed for HIV patients treated with ART and other IMIDs treated with IMA, respectively. These models will be repeated for less severe COVID-19 infections, all-cause deaths, and COVID-19-related deaths. Similarly, these models will be repeated to compare the percentage of IMA treatment discontinuation or spacing as well as the percentage of hospitalizations for an IMID flare or HIV complication (respectively). Where possible and relevant, we will compare the effect of the different types of IMA or ART and the effect of co-treatments on these same endpoints.

Data management

Data sources

Data source(s), other

Système National des Données de Santé "SNDS" France

Data sources (types)

Administrative healthcare records (e.g., claims)

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