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

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/44457

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 institution and networks

Institutions

Assistance Publique - Hôpitaux de Paris (AP-HP)

France
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Institution
Hospital/Clinic/Other health care facility

Contact details

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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
(J05AG) Non-nucleoside reverse transcriptase inhibitors
(J05AR) Antivirals for treatment of HIV infections, combinations
(J05AE) Protease inhibitors
(J05AX) Other antivirals
(L04AC) Interleukin inhibitors
(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors
(L03AB) Interferons
(L04AX03) methotrexate
(L01XC02) 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 data (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