Immunological adverse effects of immune checkpoint inhibitors (ICIMMUN)

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104677

EU PAS number
EUPAS104661

Study ID
104677

DARWIN EU® study
No

Study countries
France

Study description
A) Immune checkpoint inhibitors (ICI) are a recent type of cancer treatment that enhances the immune response against cancer cells. They have received marketing authorisation in various cancers, with a first administration in post-autorisation marketing in France in 2012. There is a growing concern about the occurrence of immune-related adverse events (irAE) related to these treatments with an increase in the number of alerts from case reports or pharmacovigilance databases.The main aim of this study is to assess the incidence rate of severe irAE globally and by type of irAE, by type of ICI and combination of ICI, in real use in France. Secondary aims are:. B) To Assess the incidence rate of severe irAE globally and by type of irAE, by type of ICI and combination of ICI, and this by type of cancer (for cancers for which sufficient numbers of patients will be treated) C) To describe how ICI are

used (characteristics of patients treated, type of ICI, combinations, successive treatments, associated treatments, depending on the type of cancer for which the number of patients treated will be sufficient) D) To describe the therapeutic management of irAE (treatment including immunosuppressants, hospitalization in resuscitation, total duration of hospitalization, associated costs, survival) E) To assess the mortality rate in patients who have developed severe irAE under ICI F) To identify risk factors for the occurrence of irAE These objectives will be also addressed in some specific subpopulations of interest. This project will provide a global overview of short and long-term irAE of ICI observed in real life conditions and to search for their risk factors, thus allowing an optimization of the management of patients.

Study status
Planned

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
Florence Tubach

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
13/01/2021

Study start date
Planned:
15/03/2019

Data analysis start date
Actual:
01/08/2021

Date of final study report
Planned:
31/12/2025

Sources of funding

- Other

More details on funding

BMS Fondation

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

Main study objective:
To Evaluate the incidence rate of severe irAE globally and by type of irAE, by type of ICI and combination of ICI, in a real situation of use in France. in real life setting in France.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(L01FX04) ipilimumab
(L01FF01) nivolumab
(L01FF02) pembrolizumab
(L01FF03) durvalumab
(L01FF04) avelumab
(L01FF05) atezolizumab
(L01FF06) cemiplimab
(L01FF07) dostarlimab

Medical condition to be studied
Neoplasm malignant

Additional medical condition(s)
Immune-mediated adverse reaction

Population studied

Age groups
Children (2 to < 12 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
Pregnant women

Estimated number of subjects
130000

Study design details

Outcomes
Time to severe immune-mediated adverse event, Time to death

Data analysis plan
In general, for the descriptions that will be conducted in relation to the different objectives, the characteristics of the population will be described in terms of mean and standard deviation or median and interquartile range (IQR) for quantitative variables. Quantitative variables will be described in terms of mean and standard deviation or median and inter-quartile range (IQR). Qualitative data will be described in terms of frequency and proportion. The cumulative incidence curves (to account for competition with death) of irAE will be estimated by the Gray method. The effect of risk factors on the occurrence of irAE will be estimated with a Fine and Gray model.

Data management

Data sources

Data source(s)
Health Search/IQVIA Health Longitudinal Patient Database

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