

Immunological adverse effects of immune checkpoint inhibitors (ICIMMUN)

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Study

Planned

Administrative details

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 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

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

ipilimumab

(L01FF01) nivolumab

nivolumab

(L01FF02) pembrolizumab

pembrolizumab

(L01FF03) durvalumab

durvalumab

(L01FF04) avelumab

avelumab

(L01FF05) atezolizumab

atezolizumab

(L01FF06) cemiplimab

cemiplimab

(L01FF07) dostarlimab

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Health Search/IQVIA Health Longitudinal Patient Database

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