OBSERVATIONAL COHORT STUDY TO CHARACTERIZE THE SAFETY OF ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION (HCT) FOR PATIENTS WITH CLASSICAL HODGKIN LYMPHOMA (CHL) TREATED WITH NIVOLUMAB

First published: 04/04/2017

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS18444

Study ID

36390

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] United States

Study description

This study is an observational, database analysis using data collected in the Center for International Blood and Marrow Transplant Research (CIBMTR) registry to describe treatment-related mortality and other complications in patients with cHL treated with nivolumab prior to receiving an allogeneic hematopoietic stem cell transplantation.

Study status

Ongoing

Research institutions and networks

Institutions

The Medical College of Wisconsin

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christopher Bond

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/06/2016

Study start date

Planned: 31/03/2017

Actual: 31/03/2017

Data analysis start date

Planned: 01/10/2022

Date of interim report, if expected

Planned: 30/06/2019

Actual: 04/06/2019

Date of final study report

Planned: 31/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CA209-835

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 analyze treatment related mortality at 6 months after an allogeneic HCT among patients with cHL who were previously treated with nivolumab, either alone or in combination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

NIVOLUMAB

Medical condition to be studied

Hodgkin's disease nodular sclerosis stage IV

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

90

Study design details

Outcomes

Treatment related mortality, Causes of death, incidence and severity of acute graft versus host disease (GVHD), hyperacute GVHD, febrile syndrome treated with corticosteroids, incidence of sinusoidal obstruction syndrome, interstitial pneumonitis, renal toxicity requiring dialysis, immune-related adverse events, events of special interest, and duration of hospital stay in patients with cHL who were treated with nivolumab, eit

Data analysis plan

The analysis for the primary objective of this study will include patients who fulfill the eligibility criteria and whom received nivolumab prior to the allogeneic HCT. The primary endpoint of treatment related mortality will be calculated using cumulative incidence function.

Data management

Data sources

Data sources (types)

Non-interventional study

Other

Data sources (types), other

A non-interventional, multicenter database including patient transplant data across multiple therapeutic areas.

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