

Long-term Follow-up of Nivolumab and Ipilimumab- (as Monotherapy and as Combination Therapy)-treated Pediatric Patients Enrolled in the Dutch Melanoma Treatment Registry (DMTR)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS29722

Study ID

39387

DARWIN EU® study

No

Study countries

 Netherlands

Study status

Ongoing

Research institutions and networks

Institutions

Dutch Melanoma Treatment Registry (DMTR)

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Institution

Contact details

Study institution contact

Transparency and Disclosure Lead ctt.group@bms.com

Study contact

ctt.group@bms.com

Primary lead investigator

Sari Hopson

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2019

Actual: 12/08/2019

Study start date

Planned: 28/06/2019

Actual: 28/06/2019

Date of final study report

Planned: 31/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb Company

Study protocol

[CA184-557_Final Redacted Protocol.pdf](#) (7.17 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition
Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The objective of this study is to evaluate long-term outcomes in pediatric patients with melanoma receiving nivolumab monotherapy, ipilimumab monotherapy, or nivolumab in combination with ipilimumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IPILIMUMAB

NIVOLUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX04) ipilimumab

ipilimumab

(L01FF01) nivolumab

nivolumab

Medical condition to be studied

Malignant melanoma

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
 - Term newborn infants (0 – 27 days)
 - Infants and toddlers (28 days – 23 months)
 - Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
-

Estimated number of subjects

100

Study design details

Outcomes

Frequency of Grade 3- and 4 treatment-related AEs and their management and outcomes. Treatment patterns, and long-term outcomes (overall survival, time to progression, progression free survival, and growth and sexual maturation) in pediatric patients with melanoma treated with Nivolumab and Ipilimumab- (as Monotherapy or as Combination Therapy).

Data analysis plan

Analyses will be descriptive and will include mean, standard deviation (SD) median, minimum, and maximum for continuous variables, and count and percentage for categorical variables. Data will be presented stratified by cohort, based on age at time of first dose of treatment (Nivolumab and Ipilimumab- as Monotherapy or as Combination Therapy). Cohort 1: patients 12 to under 18 years of age and Cohort 2: patients under 12 years of age.

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 sources (types)

[Disease registry](#)

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