

A Non-Interventional Post-Authorisation Safety Study (PASS) of Inotuzumab Ozogamicin to Characterize Complications Post-Hematopoietic Stem Cell Transplantation (HSCT) Following Inotuzumab Ozogamicin Treatment in Adult and Pediatric Patients with B-Cell Precursor Acute Lymphoblastic Leukemia (ALL).

First published: 13/03/2018

Last updated: 02/07/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS23056

Study ID

43069

DARWIN EU® study

No

Study countries

 United States

Study description

This non-interventional post-authorization safety study (PASS) will use de-identified healthcare data from the CIBMTR database. The study will evaluate safety outcomes post-HSCT in patients who have relapsed or refractory B-cell precursor ALL who have been treated with inotuzumab ozogamicin prior to proceeding to HSCT. The study will utilize all relevant data available in the Center for International Blood and Marrow Transplantation Research (CIBMTR) database from US transplant centers for a 5 year period following the approval of inotuzumab ozogamicin in the US (i.e. 18 August 2017 -17 August 2022).

Study status

Finalised

Research institutions and networks

Institutions

Center for International Blood and Marrow
Transplant Research (CIBMTR)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

KOFI ASOMANING kofi.asomaning@pfizer.com

Study contact

kofi.asomaning@pfizer.com

Primary lead investigator

KOFI ASOMANING

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2018

Actual: 19/04/2018

Study start date

Planned: 18/08/2018

Actual: 18/08/2018

Data analysis start date

Planned: 18/08/2018

Actual: 18/08/2018

Date of interim report, if expected

Planned: 28/02/2019

Actual: 20/02/2019

Date of final study report

Planned: 28/02/2023

Actual: 18/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

[INO PASS NI Study Protocol_FINAL.pdf](#) (452.64 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Other study registration identification numbers and links

B1931028

Methodological aspects

Study type

Study type

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
Disease epidemiology
Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Based on collected data obtained from CIBMTR registry, the following will be evaluated in adult and pediatric patients with B-cell ALL who received inotuzumab ozogamicin and proceeded to HSCT: • Patient-, disease- and HSCT-related characteristics, including details of all prior anti-cancer therapies, • Timing of inotuzumab ozogamicin treatment prior to HSCT, • Transplant-related mortality

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorisation safety study

Study drug and medical condition

Medical condition to be studied

B-cell type acute leukaemia

Population studied

Short description of the study population

The study population focused on all adult and pediatric US patients with B-cell precursor acute lymphoblastic leukemia (ALL) treated with inotuzumab ozogamicin post-hematopoietic stem cell transplantation (HSCT) identified from the CIBMTR database between 18 August 2017 to 17 August 2022.

Inclusion Criteria:

1. A record of B-cell precursor ALL diagnosis for adult and pediatric patients receiving dispensation/prescription of inotuzumab ozogamicin prior to or at the time of the dispensation/prescription.
2. At least 1 dose of inotuzumab ozogamicin prior to proceeding to HSCT.
3. Received HSCT from a US transplant center.

Exclusion Criteria:

Only data from patients who have consented will be used in this study.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days - 23 months)
- Term newborn infants (0 - 27 days)
- 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)
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Special population of interest

Other

Special population of interest, other

Acute lymphoblastic leukemia patients

Estimated number of subjects

1.000

Study design details

Outcomes

1. Patient-, disease- and HSCT-related characteristics, including details of all prior therapies, 2. Timing of inotuzumab ozogamicin treatment in relation to HSCT, 3. Transplant-related mortality (non-relapse mortality), non-transplant related mortality, relapse, and OS in the first 180 days, 4. Post-HSCT adverse events of interest, including VOD/SOS in the first 100 days, 5. COD.

Data analysis plan

There will be no hypothesis testing in this study. All statistical analyses performed will be descriptive. For any p-value reported, there will be no adjustment for multiplicity and no definite conclusion should be made based on the p-value.

Documents

Study results

[B1931028 Inotuzumab Final Study Report ABSTRACT 18FEB2023.pdf](#) (130.44 KB)

Study report

[B1931028 Inotuzumab Final Study Report 18Feb2023.pdf](#) (3.09 MB)

[B1931028 Inotuzumab Interim Report 2_20 Feb 2020 V1_Final.pdf](#) (1.74 MB)

[B1931028 Inotuzumab Interim Report 3 Final 17Feb2021.pdf](#) (2.59 MB)

[B1931028_INOTUZUMAB INTERIM REPORT 4 FINAL_18 FEB 2022.pdf](#) (2.68 MB)

[InO_Study B1931028_Interim report 1_FINAL.pdf](#) (1.68 MB)

Study, other information

[B1931028 Inotuzumab Interim Report 2_20 Feb 2020 V1_Final.pdf](#) (1.74 MB)

[B1931028 Inotuzumab Interim Report 3 Final 17Feb2021.pdf](#) (2.59 MB)

[B1931028_INOTUZUMAB INTERIM REPORT 4 FINAL_18 FEB 2022.pdf](#) (2.68 MB)

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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)

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