A Multi-country, Non-interventional, Retrospective Drug Utilization Study in Haematological Malignancy Patients Treated for Probable or Proven Invasive Aspergillosis (AmBiVor)

First published: 17/05/2023

Last updated: 22/04/2025

Study Finalised

Administrative details

EU PAS number

EUPAS104818

Study ID

105892

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France

- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

GS-EU-131-6385: This was a real-world, non-interventional, multi-country, retrospective chart review study using patient medical record data collected from 15 hospitals in 5 European countries (Belgium, France, Germany, Spain, and the United Kingdom (UK)). This was a study of Haematological malignancy patients (patients who have undergone Haematopoietic stem-cell transplantation HSCT, acute myeloid leukemia AML, myelodysplastic syndromes MDS and acute lymphoblastic leukaemia ALL) with a diagnosis of documented probable or proven IA (Invasive Aspergillosis) and who received at least 1 dose of AmBisome or voriconazole as primary treatment from 01 January 2014 to 31 December 2019. The primary objective of this study was to describe demographic, clinical and treatment patterns/sequences in haematologic malignancy patients treated either with AmBisome or voriconazole as primary treatment for the index proven or probable IA.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

Institution | Pharmaceutical company

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/12/2022

Study start date

Planned: 22/05/2023

Actual: 27/06/2023

Date of final study report

Planned: 28/02/2025

Actual: 11/02/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-EU-131-6385 - appendix-16.1.-protocol_f-redact_reduced.pdf(5.25 MB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The primary objective of the study was to describe demographic, clinical, and treatment patterns/sequences in haematologic malignancy patients treated either with AmBisome or voriconazole as primary treatment for the index proven or probable IA.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VORICONAZOLE

AMBISOME

Medical condition to be studied

Aspergillus infection

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

400

Study design details

Outcomes

Demographic, clinical, and treatment patterns, 42-day overall survival (OS) in haematological malignancy patients with IA treated with either AmBisome or voriconazole as primary treatment, percentage AmBisome- and voriconazole-treated patients that experience adverse events of special interests and any AEs leading to treatment discontinuation or modification, and time to first nephrotoxicy and/or hepatotoxicity during the follow-up period.

Data analysis plan

Descriptive statistics were tabulated for the demographic and clinical characteristics and outcome variables. In all cases, point estimates as well as the corresponding two-sided 95% confidence intervals (CIs) were presented.
No missing value imputation was performed.
Treatment sequence was visualized through Sankey diagrams.
The secondary objective was to estimate the 42-day OS of patients treated with AmBisome and of patients treated with voriconazole. OS and time to first

nephrotoxicity and hepatotoxicity were described using Kaplan-Meier methods and reported using descriptive statistics with 95% CIs and survival curves.

Documents

Study report

GS-EU-131-6385-CSR abstract_f-redact.pdf(577.61 KB)

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)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No