Non-Interventional Post-Authorisation Safety Study (NI-PASS) as an effectiveness check of an additional Risk Minimisation Measure (aRMM) (Direct Healthcare Professional Communication [DHPC]) for Bendamustine

First published: 14/05/2020

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34255

Study ID

41682

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

This study will be carried out to evaluate the effectiveness of an additional risk minimization measure (aRMM) (a Direct Healthcare Professional Communication DHPC letter) for bendamustine. The purpose of this study is to evaluate all-cause mortality and serious and fatal infections occurring in pre- and post-DHPC dissemination periods for new users of bendamustine during these periods, as well as for new users of other alkylating drugs similar to bendamustine (i.e. cyclophosphamide for indolent non-Hodgkin's lymphoma (iNHL), chlorambucil for chronic lymphocytic leukemia (CLL), melphalan for multiple myeloma (MM)) in populations in four European countries. Additionally, the other purpose of this study is to quantify and characterise approved and off-label use of bendamustine and other alkylating drugs similar to bendamustine (alternative treatments) in new users in pre- and post-DHPC dissemination periods in populations from four European countries.

Study status

Finalised

Research institutions and networks

Institutions

Real World Solutions, IQVIA

Netherlands

United Kingdom (Northern Ireland)

First published: 28/04/2011

Last updated: 22/03/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

Clinical Trial Registration Department

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Study contact

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Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/12/2019

Actual: 09/12/2019

Study start date

Planned: 30/06/2020

Actual: 26/06/2020

Date of interim report, if expected
Actual: 26/05/2021

Date of final study report
Planned: 31/03/2023

Actual: 19/04/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe B.V.

Study protocol

6231-ma-3264-clrp-02-disc01-en-final-02.pdf (1.6 MB)

6231-MA-3264_Bendamustine NI-PASS_Protocol_v7.0-Disclosure-Redacted (1).pdf (1.19 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 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

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate all-cause mortality and serious and fatal infections occurring in pre- and post-DHPC dissemination periods for new users of bendamustine and new users of other alkylating drugs similar to bendamustine, and to quantify and characterise approved- and off-label use of bendamustine and other alkylating drugs similar to bendamustine in new users in pre- and post-DHPC dissemination periods.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Population studied

Short description of the study population

The study cohort included new users of bendamustine or similar alkylating drugs for treating indolent non-Hodgkin’s lymphoma (iNHL), chronic lymphocytic leukemia (CLL), or multiple myeloma (MM) during the pre-direct healthcare professional communication (DHPC) dissemination period (01 April 2015 – 31 March 2017) or the post-DHPC dissemination period (01 September 2017 – 31 August 2019).
the study included single patient in either the bendamustine cohort or the cohort of alkylating drugs similar to bendamustine in the same period. The included patients were expected to be indicative of patients in the general population.

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)

Estimated number of subjects

21091

Study design details

Outcomes

-Study A: All-cause mortality, serious and fatal infections -Study B: Approved- and off-label use of bendamustine and alkylating drugs similar to bendamustine, -Study A: Hepatitis B reactivation, myelosuppression, use of anti-infective drugs, use of anti-infective drugs used for prophylaxis of opportunistic infections (PJP, VZV, CMV), frequency of laboratory testing for CD-4 positive T-cell levels in outpatient settings. -Study B: Concurrent use of bendamustine with rituximab, obinutuzumab, or idelalisib

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Data analysis plan

Study A: The incidence rates and corresponding 95% CIs of safety event outcomes will be calculated by dividing the number of observed events by person-time exposure. Results for the pre- and post- DHPC dissemination periods will be presented separately. The main study results will be stratified by country. Study B: The proportion of new users of bendamustine or alkylating drugs similar to bendamustine with any observed off-label use during the study period (pre- and post-DHPC dissemination separately) will be calculated by dividing the number of new users with any off-label use by the total number of new users, and 95% CI will be calculated. The proportion of new users of bendamustine or alkylating drugs similar to bendamustine with off-label use at the time of new use will be calculated together with 95% CIs. Results for the pre- and post-DHPC dissemination periods will be presented separately. The main study results will be stratified by country.

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), other

Hospital Episodes Statistics

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Physician survey

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