Healthcare Providers’ Awareness of the risks and safe use conditions associated with BLINCYTO®: A REMS Assessment Survey (20170108)

First published: 14/06/2017

Last updated: 21/12/2019

Study Finalised

Administrative details

EU PAS number

EUPAS19116

Study ID

32897

DARWIN EU® study

No

Study countries

☐ United States

Study description

This cross-sectional study is to evaluate the effectiveness of the BLINCYTO Risk Evaluation and Mitigation Strategy (REMS) Program among healthcare providers (HCPs) who have used BLINCYTO for patients in the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) in the United States. Specifically, the study is to determine the level of awareness and understanding of the key risks (cytokine release syndrome, neurologic toxicities, and preparation and administration errors,) and safe use conditions associated with BLINCYTO therapy. The REMS surveys were conducted at 18 months and 3 years, and will be conducted at 5 years and 7 years after the launch of BLINCYTO. In this 5-year survey, at least 300 completed surveys will be targeted, including at least 100 prescribers, 100 nurses, and 100 hospital and/or home healthcare pharmacists. A threshold knowledge score of 80% will be used to evaluate a minimum acceptable level of understanding of the key risk messages.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2019

Actual: 29/03/2019

Study start date

Planned: 21/08/2019

Actual: 25/09/2019

Data analysis start date

Planned: 21/09/2019

Actual: 15/10/2019

Date of final study report
Planned: 06/12/2019

Actual: 14/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

Protocol 2017-04-20 redaction 2017-05-23.pdf(273.6 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To determine the level of awareness on the risks and safe use conditions associated with BLINCYTO therapy and certain aspects of the BLINCYTO REMS Program among healthcare providers (HCPs) who have used BLINCYTO for patients in the treatment of B-cell precursor acute lymphoblastic leukemia (ALL)

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Philadelphia chromosome negative

Precursor B-lymphoblastic lymphoma refractory

B-cell type acute leukaemia

Population studied

Short description of the study population

Healthcare Providers’ (HCPs) who have prescribed, dispensed, prepared and/or administered BLINCYTO in the US in the past 12 months outside the clinical trial setting.

Inclusion criteria includeed HCPs, defined as prescribers [MDs, DOs, Physician Assistants (PAs), Nurse Practitioners (NPs)], nurses (RNs, BSNs), and hospital and/or home healthcare pharmacists who have prescribed, dispensed, prepared and/or administered BLINCYTO therapy to patients outside of the clinical trial setting in the past 12 months.

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

300

Study design details

Outcomes

• HCP is aware of the risk of cytokine release syndrome associated with use of BLINCYTO• HCP is aware of the risk of neurologic toxicity associated with use of BLINCYTO • HCP is aware of the risk of preparation and administration errors associated with use of BLINCYTO, HCP is aware of the indication for BLINCYTO

Data analysis plan

In general, analyses will be performed for prescribers, nurses, and pharmacists separately, as well as for the pooled group of HCPs to assess the effectiveness of the entire REMS communication plan of BLINCYTO. Demographics and other characteristics of the HCPs will be summarized using proportions. For each survey question, the proportion and 95% CI of each response option including 'not sure' will be reported. For each knowledge question, the proportion of HCPs selecting the correct response and corresponding 95% confidence interval will be calculated.

Documents

Study results

20190092 (20170108) csr-20190092-results abstract_public-redacted-approved.pdf(133.12 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)

Other

Data sources (types), other

Cross-sectional survey, primary data collection

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