A cross-sectional survey of patients and caregivers receiving Blincyto in routine clinical practice in Europe to evaluate the effectiveness of additional risk minimisation measures

First published: 22/02/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32768

EU PAS number

EUPAS17829

Study ID

32768

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain
- ☐ United Kingdom

Study description

Educational materials targeting patients /caregivers and HCPs (physicians, nurses and pharmacists) have been implemented to help minimize the risks of neurological events and the potential for medication errors (MEs). A survey of patients and caregivers will help assess whether the processes put in place for the Blincyto educational efforts are effective in achieving a sufficient level of receipt and knowledge.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

☐ United States

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Institution

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/09/2016

Actual: 05/09/2016

Study start date

Planned: 29/09/2017

Actual: 10/08/2017

Data analysis start date

Planned: 29/03/2019

Actual: 28/03/2019

Date of final study report

Planned: 29/11/2019

Actual: 13/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20150228 Protocol Ver 1 0 2016-10-18 redaction_Marked.pdf(2.84 MB)

01.02.06 Public Redacted Protocol Ver 1.0 2016-11-06 English.pdf(1.98 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

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:

The primary objectives of the study are to describe receipt of the educational materials and knowledge about the patient/caregiver educational materials, among patients with Ph– R/R B-precursor ALL receiving Blincyto and their caregivers.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

BLINATUMOMAB

Medical condition to be studied

Acute lymphocytic leukaemia

Population studied

Short description of the study population

1. Patient/caregiver completing questionnaire is 18 years of age or older.

2. Patient and/or caregiver of a patient with Ph- R/R B-precursor ALL who has received Blincyto as an outpatient.

3. Patient/caregiver completing questionnaire can read and understand the native language of the country in which the study is being conducted.

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

100

Study design details

Outcomes

Proportion of subject who received the brochure, a mean score of knowledge questions answered correctly, Behaviour, understanding and usage

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Data analysis plan

Categorical data will be summarized by counts and percentages. Continuous data will be summarized using number, mean, standard deviation (SD), median, quartiles, minimum and maximum and in the case of non-normally distributed data, median, range and interquartile range. 95% confidence intervals will be presented to three decimalplaces. The statistical analysis will include a summary of the study conduct, a descriptive analysis and the analysis of the objectives.

Documents

Study results

20150228 Observational Research Study Report Published Report_Redacted.pdf (153.97 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional 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