Expanded access of Blincyto® in patients with acute lymphoblastic leukaemia: a retrospective observational study (Neuf Study) (20160441)

First published: 15/08/2017

Last updated: 05/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50762

EU PAS number

EUPAS19961

Study ID

50762

DARWIN EU® study

No

Study countries

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

Study description

The primary objective is to describe the clinical characteristics and treatment patterns of patients with B precursor acute lymphoblastic leukemia, having received Blincyto® in the expanded access setting and identify clinically relevant subgroups

Study status

Finalised

Research institutions and networks

Institutions

Amgen

☐ United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 55 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: 09/06/2017

Actual: 07/09/2017

Study start date

Planned: 15/01/2018

Actual: 11/01/2018

Data analysis start date

Planned: 28/08/2018

Actual: 04/12/2018

Date of final study report

Planned: 30/09/2020

Actual: 14/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160441 Summary Protocol V1.0.pdf(80.76 KB)

EUPAS19961-23311.pdf(175.25 KB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to describe the clinical characteristics and treatment patterns of patients with B precursor acute lymphoblastic leukemia, having received Blincyto in the expanded access setting and identify clinically relevant subgroups

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, observational, multi-centre study

Study drug and medical condition

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

BLINATUMOMAB

Medical condition to be studied

B precursor type acute leukaemia

Population studied

Short description of the study population

The study population involved patients with B-precursor acute lymphoblastic leukemia (ALL) treated with Blincyto reported from five countries: France, Italy, Spain, UK and Russia identified from the 1st January 2014 up until 30th June 2017.

Inclusion criteria:

- B-precursor ALL patients who have initiated Blincyto in an expanded access setting from 1st January 2014 up until 30th June 2017.

Exclusion:

- Patients enrolled in Amgen expanded access protocol 20130320.
- Patients who do not provide informed consent, where required per country regulations.
- Patient’s medical chart is not available for data extraction.

Age groups

Paediatric Population (< 18 years)

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)

Special population of interest

Other

Special population of interest, other

Acute lymphoblastic leukemia patients

Estimated number of subjects

350

Study design details

Outcomes

To describe the clinical characteristics and treatment patterns of patients with B precursor ALL, having received Blincyto in the expanded access setting and identify clinically relevant subgroups, To describe the effectiveness of Blincyto within identified subgroups as outlined in Section 9.6.2.5 of the protocol To describe Blincyto utilization within identified subgroups as outlined in Section 9.6.2.5 of the protocol

Data analysis plan

All analyses will be descriptive. Continuous variables will be summarized by mean, median, standard deviation, lower and upper quartiles, and minimum and maximum values. Categorical variables will be summarized by number and percentage of patients in each category. For categorical outcomes, 95% confidence intervals (CIs) will also bepresented where appropriate. For time-to-event endpoints, Kaplan-Meier (KM) curvesand KM proportions at select time points, the number of subjects with events and thenumber of subjects censored will be used to summarise the data. Analyses will bepresented by the identified

clinically relevant subgroups (listed in Section 9.7.2.5 of the protocol and identified by means of the primary endpoints), country and year of Blincyto initiation.

Documents

Study results

01.47.01.02 Observational Research Study Report Redacted.pdf(226.53 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical records

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