Retrospective Multicenter Study Describing Baseline Clinical Characteristics and Outcomes in BLINCYTO® Treated Adult Patients With Relapsed or Refractory B-cell Precursor ALL Stratified by Baseline Disease Burden and Cytoreductive Therapy (20200012)

First published: 12/10/2020

Last updated: 22/01/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49266

EU PAS number

EUPAS37395

Study ID

49266

DARWIN EU® study

No

Study countries

United States

Study description

This observational retrospective study will be conducted at 5 sites. Around 200 subjects with relapsed or refractory B-cell precursor acute lymphoblastic leukemia who have initiated treatment with blinatumomab are planned to be included in this study. The planned study period is approximately 5 and a half years. Information will be collected to describe the baseline and clinical characteristics among the subjects. The study was cancelled on July 31, 2022

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

University of California

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Memorial Sloan Kettering Cancer Center New York, USA, City of Hope California, USA, Cleveland Clinic Ohio, USA, University of California San Francisco California, USA, Fred Hutchinson Cancer Center Washington, USA

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: 01/11/2020

Actual: 07/10/2020

Study start date
Planned: 03/10/2022

Data analysis start date
Planned: 02/01/2023

Date of final study report
Planned: 30/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original blinatumomab 20200012 .pdf(3.35 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Protocol number - 20200012

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective of this study is to describe outcomes of blinatumomab treatment among four groups of subjects.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute lymphocytic leukaemia

Additional medical condition(s)

Relapsed or refractory B-cell precursor acute lymphoblastic leukemia

Population studied

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

200

Study design details

Outcomes

Estimate proportion of patients receiving complete remission (CR) following blinatumomab treatment for relapsed or refractory acute lymphoblastic

leukemia (R/R ALL) by baseline disease burden and cytoreductive therapy patient subgroups. Estimate disease-related patient outcomes and adverse events by baseline disease burden and cytoreductive therapy patient subgroups.

Data analysis plan

This study is a retrospective analysis of treatment outcomes among subject with relapsed or refractory B-cell precursor treated with blinatumomab. Descriptive summaries of subject characteristics among all subjects and among four groups (Groups 1-4) will be generated from all covariates. Counts and proportions with 95% confidence intervals (CIs) will be estimated for binary/categorical endpoints. Continuous endpoints will be described using means, standard deviations, medians and interquartile ranges, minima, and maxima. Time-to-event endpoints will be estimated with Kaplan-Meier (KM) curves and medians with associated 95% CIs, 6-month and 12-month survival proportions with associated 95% CIs will also be estimated.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Institutional databases

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