# 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

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**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

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**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.

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**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

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**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