Overall survival and incidence of adverse events in B-cell acute lymphoblastic leukemia (ALL) patients after allogeneic stem cell transplant: blinatumomab vs non-blinatumomab chemotherapy-- an analysis of the Center for International Blood and Marrow Transplant Research database (20170610) (Transplant outcomes among ALL in CIBMTR)

First published: 02/03/2020

Last updated: 12/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS33745

Study ID

34227

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Canada
- [ ] Croatia
- [ ] Cyprus
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain

- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Networks

Center for International Blood and Marrow Transplant, Milwaukee, WI

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: 16/10/2018

Actual: 16/10/2018

Study start date

Planned: 13/03/2020

Actual: 18/03/2020

Data analysis start date

Planned: 01/10/2024

Actual: 01/10/2024

Date of final study report

Planned: 30/04/2025

Actual: 17/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 0.9 2020-02-13 English.pdf (774.17 KB)

Protocol-Published Original blinatumomab 20170610 .pdf (736.92 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To assess outcomes of blinatumomab and non-blinatumomab regimens as transplant enabling therapy in ALL patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

blyncito

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

BLINATUMOMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX07) blinatumomab

blinatumomab

Medical condition to be studied

B-cell type acute leukaemia

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1000

Study design details

Outcomes

1. Estimate 100-day mortality

2. Estimate the incidence of graft versus host disease (GVHD) (acute and chronic), Estimate 3-year overall survival (OS)Leukemia-free survival (LFS)Incidence of disease relapse Incidence of transplant-related mortality (TRM)Incidence of veno-occlusive disease/sinusoidal obstructive syndrome Incidence of new malignancies Incidence of GVHD by severity (acute and chronic)Incidence of early (<100 days) infections Incidence of persistent post-transplant B-cell depletion

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Data analysis plan

Descriptive summary of patient characteristics for all groups will be generated from all covariates specified in covariates of interest section. To estimate the incidence and risk of the outcomes of interest, the incidence proportion will be described for all outcomes.

Time-to-event analyses will be described using KM method for OS and LFS, cumulative incidence method for competing risk outcome events for median and probabilities at fixed time points.

Estimates will be generated for all groups.

If at least 219 N-BL SOC patients are identified in the study, propensity scores will be estimated for the propensity of treatment with blinatumomab based on covariates listed. Adjustment method for baseline covariates between r/r BL only and r/r N-BL SOC groups will be evaluated using inverse probability of treatment weighting and the average treatment effect method.

Weighted comparisons between groups will be made by logistic or Cox regression models estimating odds ratio and hazard ratio.

Documents

Study report

20170610_ORSR_17APR2025_Abstract_Redacted.pdf (121.28 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)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown