Evaluation of Long-term Safety in Paediatric Patients With B-precursor Acute Lymphoblastic Leukemia (ALL) who Have Been Treated With Either Blinatumomab or Chemotherapy, Followed by Transplantation (20180130) (Paediatric long-term follow up study)

First published: 10/03/2020

Last updated: 25/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS33862

Study ID

41742

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Brazil
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Czechia
- [ ] Finland
- [ ] Greece
- [ ] Israel
- [ ] Italy
- [ ] Mexico
- [ ] Poland
- [ ] Spain
- [ ] Taiwan
- [ ] Türkiye
- [ ] United States

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

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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: 30/05/2020

Study start date

Planned: 30/06/2021

Actual: 24/06/2021

Data analysis start date

Planned: 24/06/2038

Date of final study report
Planned: 09/12/2038

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 2019-11-11 English.pdf (1.42 MB)

Protocol-Published Amendment blinatumomab 20180130 6 .pdf (1.33 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The overarching aim of this study is to describe the long-term safety profile of B-precursor ALL paediatric patients who have been treated with blinatumomab or chemotherapy prior to undergoing haemopoietic stem cell transplant.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BLINCYTO

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)

Estimated number of subjects

298

Study design details

Outcomes

• To estimate incidence of neuropsychomotor developmental impairment, endocrine impairment, neurological impairment, and immune system impairment (including autoimmune disorders and vaccine failure),
• To estimate the incidence of Haemopoietic Stem Cell Transplant (HSCT) related adverse events (AEs)
• To estimate the incidence of subsequent relapse of leukemia including in the central nervous system (CNS)
• To estimate the cumulative incidence of long term AEs
• To estimate the incidence of secondary malignant formation
• To estimate overall survival

Data analysis plan

For categorical outcomes, 95% confidence intervals (CIs) will also be presented where appropriate. For time-to-event endpoints, Kaplan-Meier (KM) curves and KM proportions at select time points, the numbers of patients with events and then number of patients censored will be used to summarize the data. A comparison between the blinatumomab versus chemotherapy group will be conducted at the final follow-up in the study pending adequate sample size is enrolled (≥ 50 patients per arm) and the blinatumomab and SOC groups are comparable. Any covariates that are not comparable between the two will be evaluated as a covariate for adjustment in the models. A multivariate logistic regression will be used to compare incidence event objectives and Cox regression will be used to compare time-to-event objectives. Also, we will conduct a propensity score weighting analysis based on the covariates collected for this study.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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