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: 04/04/2024

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?

No

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

Name of medicine

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

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