A retrospective analysis of overall response and survival to 1st+ salvage therapy in T-cell and 2nd+ salvage therapy in B-cell pediatric acute lymphoblastic leukemia (20180065) (Retrospective pediatric ALL retrospective response)

First published: 21/12/2018

Last updated: 30/01/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45070

EU PAS number

EUPAS27121

Study ID

45070

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Canada
- ☐ Germany
- ☐ Italy
- ☐ United States

Study status

Finalised

Research institutions and networks

Institutions

Amgen

☐ United States

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Institution

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: 01/08/2019

Actual: 01/08/2019

Study start date

Planned: 01/12/2019

Actual: 01/12/2019

Data analysis start date

Planned: 27/06/2024

Actual: 27/06/2024

Date of final study report

Planned: 31/12/2024

Actual: 06/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Assess the complete remission response rates among pediatric patients treated for relapsed or refractory acute lymphoblastic leukemia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

T-cell type acute leukaemia

B-cell type acute leukaemia

Additional medical condition(s)

T-cell and B-cell pediatric acute lymphoblastic leukemia

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

1000

Study design details

Outcomes

Complete remission rate, event free survival, overall survival, transplant rate.

Data analysis plan

The primary objective of describing the proportion of patients achieving a CR and BOR after salvage therapy will be estimated as a proportion with a 95% CI. Patients will be categorized according to standard hematologic definitions of response. The secondary endpoint of CR+CRp will estimate the proportion of patients achieving a CR with a 95% CI. BOR after salvage therapy will be estimated as a proportion for each response with a 95% CI. MRD will be assessed among patients achieving CR+CRp. Secondary endpoints EFS and OS will be described as a median in months with a 95% CI by the Kaplan-Meier method. KM curves of EFS and OS will be plotted. EFS and OS 3-, 6- 12-, 24-, 60-month probability survival point estimates will be calculated. Additionally, the proportion of patients that undergo HSCT will also be calculated with a 95% CI, particularly among patients who achieve a CR.

Documents

Study results

20180065 Abstract ORSR 10Jan25.pdf(751.21 KB)

Data management

Data sources

Data sources (types)

Disease registry

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