An observational study of patients with Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukemia in the US (20150253)

First published: 20/06/2016

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS13794

Study ID

40386

DARWIN EU® study

No

Study countries

☐ United States

Study description

This observational cohort study aims to characterize current real-world treatment and outcomes among patients with Philadelphia chromosome-negative (Ph-) R/R ALL. The study will involve a series of reviews of medical records of patients initiating treatment for Ph- R/R ALL between January 2013 and March 2019 at approximately 20-30 selected clinical centers in the US. This study will describe patient characteristics and treatment patterns among Ph- R/R ALL patients. In addition, the study will assess drug utilization, healthcare resource utilization, and treatment effectiveness and safety among Ph- R/R ALL patients in the salvage treatment setting.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

University of Maryland Greenbaum Cancer Center Baltimore, MD, USA, University of Southern California, Norris Comprehensive Cancer Center

Los Angeles, CA USA, McFarland Clinic Ames, IA, USA, City of Hope National Medical Center Duarte, CA, USA, NY Presbyterian/Weill Cornell Medical Center New York, NY, USA, University of Pennsylvania Philadelphia, PA, USA, Rush University Medical Center Chicago, IL, USA, Karmanos Cancer Institute Detroit, MI, USA, Thomas Jefferson University Hospital Philadelphia, PA, USA, John Theurer Cancer Center at Hackensack University Medical Center Hackensack, NJ, USA

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 26/02/2016

Study start date
Planned: 28/06/2016

Actual: 30/06/2016

Data analysis start date
Planned: 31/03/2020

Actual: 31/03/2020

Date of final study report
Planned: 31/03/2021

Actual: 30/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20150253_01.02.06 Public Redacted Protocol Ver 1.0 2018-04-19 English.pdf
(1.59 MB)

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe treatment patterns, drug utilization, and healthcare resource utilization in patients with Ph- R/R ALL

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BLINATUMOMAB

Medical condition to be studied

B precursor type acute leukaemia

Population studied

Short description of the study population

The study population will include patients initiating treatment for Philadelphia chromosome-negative (Ph-) R/R ALL between January 2013 and March 2019 at participating clinical sites in the US.

Medical records of all patients initiating treatment for Ph- R/R ALL at participating clinical centers in the US between January 2013 and March 2019 will be eligible for inclusion.
1. Medical records of patients participating in clinical trials will be included for purposes of comprehensively describing the treatment paths of Ph- R/R ALL patients. Other study objectives will be evaluated among these medical records up to the time the patient enrolls into a clinical trial, however patient data after enrollment in a clinical trial will not be collected.
2. Medical records of patients with Philadelphia chromosome-positive (Ph+) disease will be excluded.
3. If informed consent is required, medical records of patients who do not provide informed consent will be excluded.

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

Other

Special population of interest, other

Acute lymphoblastic leukemia patients

Estimated number of subjects

200

Study design details

Outcomes

Drug utilization, treatment patterns, healthcare resource utilization, Best response to salvage treatment, incidence of selected adverse events, overall survival following salvage treatment, minimal residual disease status following salvage treatment, relapse-free survival, receipt of allogeneic hematopoietic stem cell transplantation

Data analysis plan

Analyses of primary and secondary objectives will be descriptive in nature. Demographic, treatment, and clinical characteristics of patients will be summarized by means, standard deviations, medians and interquartile ranges, minima, and maxima for continuous variables and by counts and proportions/percentages for categorical variables. As a measure of precision, a 95% confidence interval will be calculated around point estimates (i.e. proportions). Descriptive analyses of primary and secondary objectives will be provided overall and by subpopulations of interest (eg, by treatment group, by line of salvage) when sample size permits.

Documents

Study results

01.47.01.01 Observational Research Study Report Published Report_Abstract_30MAR2021.pdf (129.42 KB)

EUPAS13794-40373.pdf (118.32 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)

Other

Data sources (types), other

Review of medical records

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