Multicenter Assessment of Treatment Outcomes in a Historical Cohort of Patients with Relapsed or Refractory Acute Myeloid Leukemia (20180232) (Retrospective relapse/refractory AML outcomes)

First published: 13/11/2018

Last updated: 08/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS26165

Study ID

49921

DARWIN EU® study

No

Study countries

Australia

Korea, Republic of

United States

Study description

Study activities on 20180232 were canceled December 31, 2023. As study activities were canceled during data analysis, no final study results are available and study report will not be authored.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

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

Planned: 31/12/2018

Actual: 31/03/2019

Study start date

Planned: 30/04/2019

Actual: 04/04/2019

Data analysis start date

Planned: 01/07/2021

Actual: 14/11/2022

Date of final study report

Planned: 31/12/2022

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:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Patient outcomes

Main study objective:

To estimate the proportion of patients achieving hematological complete remission (CR) following salvage treatment for relapsed or refractory (R/R) acute myeloid leukemia (AML).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute myeloid leukaemia

Population studied

Age groups

- 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)

Estimated number of subjects

3000

Study design details

Outcomes

Complete remission after salvage therapy, Complete remission with incomplete hematologic recovery, best response, remission duration, stem cell transplant proportion, overall survival, event free survival

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Data analysis plan

Descriptive analysis of complete remission proportions (N CR/N received therapy), duration of complete remission, event free survival, overall survival, stem cell transplant proportion.

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No