DARWIN EU® - Acute myeloid leukaemia: incidence, patient characteristics, treatments, and survival in the period 2015–2024

First published: 08/10/2025

Last updated: 08/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000773

Study ID

1000000773

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Finland

- [ ] Germany
- [ ] Netherlands
- [ ] Norway
- [ ] Spain

Study description

Acute myeloid leukaemia (AML) is an aggressive haematological malignancy characterised by the uncontrolled proliferation of myeloid precursors. It primarily affects older adults but is also diagnosed in children.
Despite advances in diagnostics and treatment, survival remains poor, especially among elderly patients.
Diagnosis relies on blast counts and genetic markers, with evolving classifications emphasising molecular features. Standard treatment includes induction chemotherapy and, in eligible patients, allogeneic stem cell transplant. Although novel targeted therapies show promise, further evidence is needed to support their safety.
This study aims to generate real-world evidence on AML incidence, patient characteristics, treatment patterns, and survival, utilising routinely collected healthcare data, to inform both clinical and regulatory decision-making.
This will be the basis for further work on dedicated algorithms from source data to improve data quality and availability in AML.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anton Barchuk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/06/2025

Actual: 16/06/2025

Study start date

Planned: 26/09/2025

Actual: 26/09/2025

Date of final study report
Planned: 30/01/2026

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

Acute myeloid leukaemia

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Cohort studies will be conducted using routinely collected health data

Main study objective:

1. To estimate the annual incidence of AML in children (<18 years old) and adults (≥18).
2. To characterise AML patients in terms of demographics, performance status, conditions, disease characteristics, measurements, and procedures.
3. To describe treatment patterns in AML patients.
4. To estimate overall survival 1, 3, and 5 years for patients with newly diagnosed AML.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute myeloid leukaemia

Population studied

Short description of the study population

For the estimation of incidence, all individuals present in the data source will be included in the denominator according to the requirements described in section 8.4 of the protocol. Only individuals with newly diagnosed AML will be included in the study for objectives 2–4.

Objective 1 inclusion criteria

• Observation in the period 01/01/2015 to 31/12/2024

• Minimum 365 days of available history before contributing to person-time at risk (except for children <1 year)

Objective 2–4 inclusion criteria

• First diagnosis of AML in the period of 01/01/2015 to 31/12/2024

• Minimum 365 days of available history before diagnosis date (except for children <1 year)

• No prior history of AML before the study period

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

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)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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 source(s)

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

The Cancer Registry of Norway

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

InGef Research Database

Netherlands Cancer Registry

The Information System for Research in Primary Care (SIDIAP)

IMI 116026 HARMONY; IMI 945406 HARMONY PLUS - HARMONY Big Data Platform

Data source(s), other

Finnish Care Register for Health Care, Hospital Universitario 12 de Octubre

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No