DARWIN EU® Prevalence of rare blood cancers in Europe

First published: 31/01/2023 Last updated: 12/06/2024





Administrative details

PURI

https://redirect.ema.europa.eu/resource/50801

EU PAS number

EUPAS50800

Study ID

50801

DARWIN EU® study

Yes

Study countries

Belgium

Germany

Netherlands

Spain

United Kingdom

Study description

In this study the prevalence of rare blood cancers (follicular lymphoma, diffuse large B-Cell lymphoma, multiple myeloma, chronic lymphocytic leukaemia, acute myeloid leukaemia, acute lymphocytic leukaemia) will be assessed.

Study status

Finalised

Research institution and networks

Institutions







University of Oxford

Networks

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

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Hungary

Netherlands

Norway

Portugal

Spain

United Kingdom

First published: 01/02/2024

Last updated 11/06/2024

Network

Contact details

Study institution contact

Edward Burn

Study contact

e.burn@darwin-eu.org

Primary lead investigator

Edward Burn

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

13/05/2022

Actual:

13/05/2022

Study start date

Planned: 01/11/2022 Actual: 01/11/2022

Date of final study report

Planned: 28/03/2023 Actual: 28/03/2023

Sources of funding

EMA

Study protocol

D2.2.3_DARWIN_EU_Study Protocol C1-001_v2.0_EU_PAS.pdf(1.04 MB)

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 list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary data collection

Main study objective:

To estimate the prevalence of rare blood cancers (follicular lymphoma, diffuse Large B-Cell Lymphoma, Multiple Myeloma, Chronic Lymphocytic Leukaemia, Acute Myeloid Leukaemia, Acute Lymphocytic Leukaemia)

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Population-based

Study drug and medical condition

Medical condition to be studied

Follicular lymphoma
Diffuse large B-cell lymphoma
Plasma cell myeloma
Chronic lymphocytic leukaemia
Acute myeloid leukaemia
Acute lymphocytic leukaemia

Population studied

Short description of the study population

The study included all individuals reported in the five European databases, including IPCI, SIDIAP, CPRD, IQVIA LPD Belgium, and IQVIA DA Germany, to determine the prevalence of haematological cancers.

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

Patients with haematological cancers

Estimated number of subjects

10000000

Study design details

Outcomes

Follicular lymphoma, diffuse Large B-Cell Lymphoma, Multiple Myeloma, Chronic Lymphocytic Leukaemia, Acute Myeloid Leukaemia, Acute Lymphocytic.

Data analysis plan

5-year partial prevalence will be estimated for each outcome of interest.

Documents

Study results

DARWIN_EU_Study_Report_C1-001_V3.2.pdf(1.49 MB)

Data management

Data sources

Data source(s)

IPCI

The Information System for Research in Primary Care (SIDIAP) Clinical Practice Research Datalink

Longitudinal Patient Data - Belgium

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No