Clinical Systematic Literature Review (SLR) of Ph(-) B-ALL in High-risk First Relapse Paediatric Patients

First published: 02/07/2021

Last updated: 04/01/2022

Study Finalised

Administrative details

EU PAS number

EUPAS41675

Study ID

44870

DARWIN EU® study

No

Study countries

United States

Study description

This study will conduct an SLR of evidence from clinical studies to assess the clinical effectiveness of treatments administered for paediatric populations (28 days - 18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-precursor Acute Lymphoblastic Leukemia (B-ALL). The review will include studies with participants in first relapse to first line treatment who were treated with any active anti-tumour treatment, including chemotherapy and Chimeric Antigen Receptor T-cell (CAR-T) therapy. The study designs eligible for inclusion in humans are: Controlled clinical trials, Observational real-world, and, single-arm studies. Electronic databases and congresses will be searched for evidence in line with NICE Health Technology Assessment (HTA) guidance. The process for study selection will be aligned with the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for the reporting of SLRs and meta-analyses.

Study status

Finalised

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: 09/10/2020

Actual: 09/10/2020

Study start date

Planned: 27/11/2020

Actual: 27/11/2020

Data analysis start date

Planned: 21/01/2021

Actual: 21/01/2021

Date of interim report, if expected

Planned: 26/02/2021

Actual: 26/02/2021

Date of final study report
Planned: 13/04/2021

Actual: 12/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original Blinatumomab 20200443.pdf (587.41 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To conduct a SLR of evidence from clinical studies (controlled and observational) to assess the clinical effectiveness of treatments administered for paediatric populations (> 28 days and <18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-ALL

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medical condition to be studied

Philadelphia chromosome negative

Population studied

Short description of the study population

The review will include studies assessing paediatric populations (< 18 years of age) with high-risk Philadelphia chromosome-negative B-precursor ALL in first relapse to first line treatment. Some studies may have used MRD to identify/define relapse/response and will also be included when different definitions used. Studies will be excluded if patients do not have B-precursor ALL, in case of clinically relevant CNS requiring treatment or evidence of current CNS involvement by ALL or if studies report 2nd relapsed patient populations. If a study included patients with clinically relevant CNS involvement as well as those without, and this study separately reports the results for each category of patients, then this study will be included and information for the patients without clinically relevant CNS involvement will be extracted if the other inclusion criteria are met.

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

0

Study design details

Data analysis plan

Identified evidence will be extracted into an Excel workbook and a qualitative synthesis developed in Word. Tabulated summaries of the studies will be provided to allow the review of the evidence available for the clinical effectiveness and safety of treatments administered for paediatric populations

(>28 days and <18 years of age) with high-risk first relapse Philadelphia chromosome-negative B-ALL, categorized by population, intervention, outcome type, and quality. The risk of bias in each included study will be assessed. Bias refers to a process at any stage of inference tending to produce results that depart from the true values. For quality assessment of clinical effectiveness studies (ie, randomised controlled trials RCTs, observational studies and single-arm studies), the Cochrane Collaboration's tool for assessing risk of bias will be used.

Documents

Study results

Paediatric ALL clinical SLR report_AMSR008_Final report_Executive Summary__12 April 2021.pdf (117.23 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

Electronic databases and congresses

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