# A Real-world Evidence on Effectiveness and Safety of Blinatumomab in Patients With B-cell Acute Lymphoblastic Leukaemia

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS106021

**Study ID**

106022

**DARWIN EU® study**

No

**Study countries**

China

**Study status**

Finalised

# Contact details

**Study institution contact**

huifen zhou zhouhuifen@suda.edu.cn

**Study contact**

zhouhuifen@suda.edu.cn

**Primary lead investigator**

huifen zhou

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 01/01/2021

Actual: 01/01/2021

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**Study start date**

Planned: 01/01/2021

Actual: 01/01/2021

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**Data analysis start date**

Planned: 31/03/2023

Actual: 31/03/2023

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**Date of final study report**

Planned: 30/06/2023

Actual: 30/06/2023

# Sources of funding

- Other

## More details on funding

The first affliated hospital of soochow university

## 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:**

Other

**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

A Real-world Evidence on Effectiveness and Safety of Blinatumomab in Patients With B-cell Acute Lymphoblastic Leukaemia

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective study

## Population studied

**Short description of the study population**

Patients with B-cell acute lymphoblastic leukaemia received treatment with blinatumomab between August 2021 and June 2023.

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**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)

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**Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

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**Estimated number of subjects**

1

## Study design details

**Outcomes**

This study showed that blinatumomab was effective in the treatment of patients with B-ALL in the frontline as well as relapsed settings and had a tolerable safety profile.

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**Data analysis plan**

In this retrospective observational study, data of patients with ND and R/R B-ALL who received at least one dose of blinatumomab between August 2021 and June 2023 were collected from electronic medical data of the Department of Haematology of the First Affiliated Hospital of Soochow, China. The primary endpoint of the study was the treatment pattern of blinatumomab therapy, including median treatment cycles, treatment days, and treatment discontinuation. Secondary endpoints included complete remission (CR) rate/CR with incomplete blood cell recovery (CRi), minimal residual disease (MRD) negativity after 2 cycles of treatment (complete MRD remission defined as MRD

< 0.01%), median and 1-year event-free survival (EFS) rate, median and 1-year overall survival (OS) rate, duration of response (DOR) and adverse events (AEs).

# 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

Other

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**Data sources (types), other**

Prescription event monitoring, Case-control surveillance database

## 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