An observational study of blinatumomab safety and effectiveness, utilisation, and treatment practices (20150136)

First published: 17/02/2017

Last updated: 14/03/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49944

EU PAS number

EUPAS17848

Study ID

49944

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Czechia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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: 16/06/2016

Actual: 16/06/2016

Study start date

Planned: 14/03/2017

Actual: 22/03/2017

Data analysis start date

Planned: 03/05/2024

Actual: 02/05/2024

Date of interim report, if expected

Planned: 08/07/2018

Actual: 03/07/2018

Date of final study report

Planned: 20/02/2025

Actual: 20/02/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Amendment blinatumomab 20150136 9 .pdf(1.91 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The first primary objective is to characterize the safety profile of Blincyto in routine clinical practice in countries in the EU by characterising specific AEs. The second primary objective is to estimate the frequency and type of medication errors identified in patient charts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BLINATUMOMAB

Population studied

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

279

Study design details

Outcomes

Incidence of specified AEs. Time to onset of first specified AEs. Summary of duration of specified AEs. Proportion of Blincyto administrations with medication errors. Incidence of AEs collected. Incidence of specified AEs and AEs collected among patient subgroups. Proportion of patient achieving CR, CR/CRh*/CRi, MRD within 2 cycles of Blincyto. Proportion of patients receiving allogeneic

HSCT. 1 year and 100 day mortality proportion after HSCT. Relapse free survival time. Disease free survival. Overall survival. Healthcare resource use. Blinicyto Utilization.

Data analysis plan

All analyses will be descriptive. Continuous variables will be summarised by mean, median, standard deviation, 25th percentile, 75th percentile, minimum and maximum. Categorical variables will be summarised by number and percentage. For categorical outcomes, 95% confidence intervals (CIs) will also be presented where appropriate. For time-to-event endpoints, Kaplan-Meier (KM) curves and estimates (median, 1st and 3rd quartile) of the time-to-event endpoint with 95% confidence intervals will be calculated, if estimable. Six, 12- and 24-month survival proportions and 95% confidence intervals will also be estimated. Subject incidence (and 95% CIs) for adverse events will be summarised and tabulated by system organ class and preferred term. Incidence tables will also be presented with respect to time on Blincyto at the patient level (incidence rate) and event level (event rate).

Documents

Study results

20150136 ORSR_Redacted.pdf(2.69 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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