A Post-authorization Safety Study to Evaluate the Incidence of and Risk Factors for Severe and Fatal Infusion-related Reactions in Participants Treated with Daratumumab (Intravenous or Subcutaneous) (HALO)

First published: 22/11/2022

Last updated: 26/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS49827

Study ID

49828

DARWIN EU® study

No

Study countries

- [ ] Brazil
- [ ] Canada
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

This single-arm, prospective observational study aims to assess the incidence of and risk factors for severe (Grades 3 to 4) and fatal (Grade 5) infusion-related reactions (IRRs) in participants treated with intravenous (IV) or subcutaneous (SC) daratumumab for the treatment of multiple myeloma (MM) in the clinical practice setting (in accordance with approved local labelling) and to characterize potential risk factors.

Study status

Ongoing

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Sitthi-Amorn

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/05/2022

Actual: 10/05/2022

Study start date

Planned: 28/11/2022

Actual: 09/12/2022

Date of final study report

Planned: 15/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen R&D, LLC

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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

Safety study (incl. comparative)

Main study objective:

To assess the risk of severe (Grades 3 to 4) and fatal (Grade 5) IRRs in participants treated with IV or SC daratumumab for the treatment of MM in the clinical practice setting and to attempt to identify potential risk factors for IRRs during daratumumab use and potential mitigation strategies.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name

DARZALEX

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

DARATUMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FC01) daratumumab

daratumumab

Medical condition to be studied

Plasma cell myeloma

Additional medical condition(s)

Severe and Fatal Infusion-related Reactions (IRRs)

Population studied

Age groups

- **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)

Estimated number of subjects

1009

Study design details

Data analysis plan

Descriptive summaries will be provided. Risk factors for IRR with grade 3 or above will be evaluated through logistic models. If deemed necessary, additional machine learning approaches such as LASSO or Elastic Net logistic regression will be explored.

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

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