# 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:** 14/04/2026

Study Finalised

## 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**

Finalised

# Research institutions and networks

## Institutions

### Johnson & Johnson

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Anna Sitthi-Amorn RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

### 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: 18/03/2026

Actual: 18/03/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen R&D, LLC

## Study protocol

11Mar2026-REDACTED_Protocol-FD-54767414NAP4001-EUPAS49827.pdf (2.19 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Non-EU RMP only

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

**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.

## Documents

**Abstract of study report**

20260407_REDACTED_CSR-Synopsis-54767414NAP4001-1900598_1904656_Disclaimer_English.pdf (734.61 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**

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