Characterize infections and outcomes developed in relapsed/refractory multiple myeloma (RRMM) patients treated with Teclistamab (SPOT)

First published: 16/01/2025

Last updated: 11/08/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000414

Study ID

1000000414

DARWIN EU® study

No

Study countries

Portugal

Study description

This is a retrospective, multicenter, observational study to primarily characterize the infections developed by triple class-exposed RRMM patients and their outcomes during Teclistamab treatment, in the Portuguese clinical practice.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

Rjaime3@its.jnj.com

Primary lead investigator

Rui Bergantim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/04/2024

Actual: 23/04/2024

Study start date

Planned: 27/02/2025

Actual: 27/02/2025

Data analysis start date
Actual: 08/03/2025

Date of interim report, if expected
Actual: 29/05/2026

Date of final study report
Planned: 08/06/2027

Study protocol

REDACTED_Protocol-FD-64007957MMY4011-1485918_1872334.pdf (2.15 MB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective, multicenter, observational study

Main study objective:

Primary Objective

1. To describe the incidence, severity, timing, management, and outcomes of infection experienced by patients under Teclistamab treatment in the first 3 months outside of clinical trials

Secondary Objectives

1. To describe the incidence, severity, timing, management, and outcomes of infection experienced by patients under Teclistamab treatment in the first 6 months outside of clinical trials;
2. To describe the prophylaxis and infections management protocols used in the Portuguese clinical practice;
3. To describe the differences in baseline characteristics between MM triple-

class exposed patients who experienced infections within the first 3 or 6 months of Teclistamab and those who did not;
4. To describe the overall response rate (partial response or better) and the best response.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TECVAYLI

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

TECLISTAMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX24) teclistamab

teclistamab

Medical condition to be studied

Plasma cell myeloma

Additional medical condition(s)

Multiple Myeloma

Study design details

Setting

Participating sites will be hospitals with hematology units specialized in treating and managing patients with RRMM in Portugal.

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)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes