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

First published: 16/01/2025

Last updated: 04/07/2025

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

Rita Jaime Rjaime3@its.jnj.com

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

Study start date

Planned: 27/02/2025

Actual: 27/02/2025

Data analysis start date
Planned: 14/02/2026

Date of final study report
Planned: 14/11/2026

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Study drug and medical condition

Name of medicine

TECVAYLI

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

TECLISTAMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX24) teclistamab

teclistamab

Additional medical condition(s)

Multiple Myeloma

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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