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

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000414

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

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 90 MG/ML - SOLUTION FOR INJECTION

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

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