A Phase 3 Randomized Study Comparing Teclistamab Monotherapy versus Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed or Refractory Multiple Myeloma who have Received 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Monoclonal Antibody and Lenalidomide

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	299
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenómica, farmacoeconómica	NO

Información

Identificador
2023-503444-13-00 (CTIS)

Cod. Protocolo
64007957MMY3006

Transicionado 2022-000928-37

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Relapsed/refractory multiple myeloma

Título Científico

A Phase 3 Randomized Study Comparing Teclistamab Monotherapy versus Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed or Refractory Multiple Myeloma who have Received 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Monoclonal Antibody and Lenalidomide

Justificación

No aportado

Objetivo Principal

To compare the efficacy of teclistamab with PVd/Kd

Variables de Evaluación Primaria

progression free survival (PFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Documented diagnosis of multiple myeloma as defined by the criteria below: (a)Multiple myeloma diagnosis according to International Myeloma Working Group (IMWG) diagnostic criteria (b) Measurable disease at screening as defined by any of the following: (1) Serum M-protein level greater than or equal to ()0.5 grams per deciliter (g/dL) (central laboratory); or (2) Urine M-protein level 200 milligrams (mg)/24 hours (central laboratory); or (3) Serum

immunoglobulin free light chain 10 milligrams per deciliter (mg/dL) (central laboratory) and abnormal serum immunoglobulin kappa lambda free light chain ratio
2. Received 1 to 3 prior lines of antimyeloma therapy including a minimum of 2 consecutive cycles of an anti- cluster of differentiation 38 (CD38) monoclonal antibody at the approved dosing regimen in any prior line and 2 consecutive cycles of lenalidomide in any prior line
3. Documented evidence of progressive disease or failure to achieve a response to last line of therapy based on investigator's determination of response by International myeloma working group (IMWG) criteria
4. Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2
5. A female participant must agree not to be pregnant, breast-feeding, or plan to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment
6. Must be willing and able to adhere to the lifestyle restrictions specified in this protocol

Criterios de Exclusión

1. Received any prior B cell maturation antigen (BCMA)-directed therapy 2. A participant is not eligible to receive PVd as control therapy if any of the following are present: (1) Received prior pomalidomide therapy, (2) Does not meet criteria for bortezomib retreatment (3) Contraindications or life-threatening allergies, hypersensitivity, or intolerance to pomalidomide or bortezomib, (4) Grade 1 peripheral neuropathy with pain or Grade greater than or equal to () 2 peripheral neuropathy as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0, (5) Received a strong cytochrome P (CYP) 3A4 inducer within 5 half-lives prior to randomization; A participant is not eligible to receive Kd as control therapy if any of the following are present:(1) Received prior carfilzomib therapy, (2) Uncontrolled hypertension, defined as an average systolic blood pressure greater than (>)159 millimeters of mercury (mmHg) or diastolic blood pressure >99 mmHg despite optimal treatment (3) Grade 2 peripheral neuropathy with pain or Grade 3 peripheral neuropathy as defined by NCI-CTCAE Version 5.0, (4) Contraindications or life-threatening allergies, hypersensitivity, or intolerance to carfilzomib (intolerance defined as prior therapy discontinued due to any adverse event [AE] related to carfilzomib) 3. Central nervous system (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma 4. Received a live, attenuated vaccine within 4 weeks before randomization 5. Plasma cell leukemia at the time of screening, Waldenstrom's macroglobulinemia, polyneuropathy, organomegaly, endocrinopathy, M-protein (POEMS) syndrome and skin changes, or primary amyloid light chain amyloidosis 6. Received a maximum cumulative dose of corticosteroids of 140 mg of prednisone or equivalent within 14 days prior to randomization

Calendario

(Última actualización: 05/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
25/11/2022	26/04/2023	26/04/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
03/04/2025	No aportado	No aportado	No aportado	No aportado

Promotor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Activo (23/01/2023)

Complejo Hospitalario Infanta Leonor

Madrid

MADRID

Activo (13/09/2023)

Hospital De León (Complejo Asistencial Universitario De León)

León

LEÓN

Activo (03/02/2023)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Activo (03/02/2023)

HOSPITAL SON LLATZER

Palma

BALEARES

Activo (19/02/2024)

Hospital Universitari Germans Trías I Pujol De Badalona

Badalona

BARCELONA

Activo (20/06/2023)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Activo (23/01/2023)

HOSPITAL UNIVERSITARIO DE JEREZ DE LA FRONTERA

Jerez de la Frontera

CÁDIZ

Cerrado (20/05/2025)

HOSPITAL UNIVERSITARIO MONTECELO

Pontevedra

PONTEVEDRA

Activo (06/10/2023)

Hospital Universitario Quironsalud Madrid

Pozuelo de Alarcón

MADRID

Activo (06/02/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Activo (31/05/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Activo (25/09/2023)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Activo (22/05/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medicamentos

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

Kyprolis 60 mg powder for solution for infusion
SOLUTION FOR INFUSION
SUBCUTANEOUS USE

Código ATC: L01XG02 - CARFILZOMIB
Principios Activos: N/A

Huérfano Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Dexamethason 8 mg GALEN® Tabletten
TABLET
ORAL

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

Imnovid 4 mg hard capsules

CAPSULE, HARD

ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA

Principios Activos: N/A

Huérfano

Experimental

VELCADE 3.5 mg powder for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

Código ATC: L01XG01 - BORTEZOMIB

Principios Activos: N/A

Experimental

teclistamab

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Principios Activos: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

Fortecortin® 2 mg Tabletten

TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

Código ATC: H02AB02 - DEXAMETASONA

Principios Activos: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Principios Activos: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Principios Activos: N/A

Experimental

Sin resultados

A Phase 3 Randomized Study Comparing Teclistamab Monotherapy versus Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed or Refractory Multiple Myeloma who have Received 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Monoclonal Antibody and Lenalidomide

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	299
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenomics, pharmacoeconomic	NO

Information

Identifier
2023-503444-13-00 (CTIS)

Protocol Code
64007957MMY3006

Transitioned 2022-000928-37

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Relapsed/refractory multiple myeloma

Scientific Title

A Phase 3 Randomized Study Comparing Teclistamab Monotherapy versus Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed or Refractory Multiple Myeloma who have Received 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Monoclonal Antibody and Lenalidomide

Rationale

Not provided

Main Objective

To compare the efficacy of teclistamab with PVd/Kd

Primary Endpoints

progression free survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Documented diagnosis of multiple myeloma as defined by the criteria below: (a)Multiple myeloma diagnosis according to International Myeloma Working Group (IMWG) diagnostic criteria (b) Measurable disease at screening as defined by any of the following: (1) Serum M-protein level greater than or equal to ()0.5 grams per deciliter (g/dL) (central laboratory); or (2) Urine M-protein level 200 milligrams (mg)/24 hours (central laboratory); or (3) Serum

immunoglobulin free light chain 10 milligrams per deciliter (mg/dL) (central laboratory) and abnormal serum immunoglobulin kappa lambda free light chain ratio
2. Received 1 to 3 prior lines of antimyeloma therapy including a minimum of 2 consecutive cycles of an anti- cluster of differentiation 38 (CD38) monoclonal antibody at the approved dosing regimen in any prior line and 2 consecutive cycles of lenalidomide in any prior line
3. Documented evidence of progressive disease or failure to achieve a response to last line of therapy based on investigator's determination of response by International myeloma working group (IMWG) criteria
4. Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2
5. A female participant must agree not to be pregnant, breast-feeding, or plan to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment
6. Must be willing and able to adhere to the lifestyle restrictions specified in this protocol

Exclusion criteria

1. Received any prior B cell maturation antigen (BCMA)-directed therapy 2. A participant is not eligible to receive PVd as control therapy if any of the following are present: (1) Received prior pomalidomide therapy, (2) Does not meet criteria for bortezomib retreatment (3) Contraindications or life-threatening allergies, hypersensitivity, or intolerance to pomalidomide or bortezomib, (4) Grade 1 peripheral neuropathy with pain or Grade greater than or equal to () 2 peripheral neuropathy as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0, (5) Received a strong cytochrome P (CYP) 3A4 inducer within 5 half-lives prior to randomization; A participant is not eligible to receive Kd as control therapy if any of the following are present:(1) Received prior carfilzomib therapy, (2) Uncontrolled hypertension, defined as an average systolic blood pressure greater than (>)159 millimeters of mercury (mmHg) or diastolic blood pressure >99 mmHg despite optimal treatment (3) Grade 2 peripheral neuropathy with pain or Grade 3 peripheral neuropathy as defined by NCI-CTCAE Version 5.0, (4) Contraindications or life-threatening allergies, hypersensitivity, or intolerance to carfilzomib (intolerance defined as prior therapy discontinued due to any adverse event [AE] related to carfilzomib) 3. Central nervous system (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma 4. Received a live, attenuated vaccine within 4 weeks before randomization 5. Plasma cell leukemia at the time of screening, Waldenstrom's macroglobulinemia, polyneuropathy, organomegaly, endocrinopathy, M-protein (POEMS) syndrome and skin changes, or primary amyloid light chain amyloidosis 6. Received a maximum cumulative dose of corticosteroids of 140 mg of prednisone or equivalent within 14 days prior to randomization

Calendar

(Last Update: 05/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
25/11/2022	26/04/2023	26/04/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
03/04/2025	Not aported	Not aported	Not aported	Not aported

Sponsor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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ceic@cfnavarra.es

Sites

Active (23/01/2023)

Complejo Hospitalario Infanta Leonor

Madrid

MADRID

Active (13/09/2023)

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Oviedo

ASTURIAS

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Jerez de la Frontera

CÁDIZ

Closed (20/05/2025)

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PONTEVEDRA

Active (06/10/2023)

Hospital Universitario Quironsalud Madrid

Pozuelo de Alarcón

MADRID

Active (06/02/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Active (31/05/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Active (25/09/2023)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Active (22/05/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medication

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

Kyprolis 60 mg powder for solution for infusion
SOLUTION FOR INFUSION
SUBCUTANEOUS USE

ATC code: L01XG02 - CARFILZOMIB
Active Principles: N/A

Orphan Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Dexamethason 8 mg GALEN® Tabletten
TABLET
ORAL

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan Experimental

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

Imnovid 4 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L04AX06 - POMALIDOMIDA

Active Principles: N/A

Orphan

Experimental

VELCADE 3.5 mg powder for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: L01XG01 - BORTEZOMIB

Active Principles: N/A

Experimental

teclistamab

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Active Principles: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

Fortecortin® 2 mg Tabletten

TABLET

ORAL USE

-

Active Principles: N/A

Experimental

ATC code: H02AB02 - DEXAMETASONA

Active Principles: N/A

Experimental

Privigen 100 mg/ml solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Active Principles: N/A

Experimental

Pomalidomide

CAPSULE, HARD

ORAL USE

-

Active Principles: N/A

Experimental

No results