A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	366
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica	Terapia génica

Información

Identificador
2023-507632-20-00 (CTIS)

Cod. Protocolo
EMN2868284528MMY3005

Transicionado 2021-003284-10

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Multiple Myeloma

Título Científico

A Phase 3 Randomized Study Comparing Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Ciltacabtagene Autoleucel versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible

Justificación

No aportado

Objetivo Principal

To compare the efficacy of DVRd followed by cilta-cel and lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy in terms of PFS and sustained MRD-negative CR

Variables de Evaluación Primaria

PFS
Sustained MRD-negative CR, defined as MRD-negative CR for at a minimum 12 months duration, with MRD status determined by NGS with a sensitivity of at least 10-5

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To further compare the efficacy of DVRd followed by cilta-cel and lenalidomide therapy
To characterize the safety of cilta-cel after DVRd therapy followed by lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy
To characterize the PK and pharmacodynamics of cilta-cel
To evaluate the PRO associated with DVRd followed by cilta-cel and lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy
To determine whether RCL is present in participants that receive ciltacel

Variables de Evaluación Secundaria

Overall response (PR or better) status and CR or better status
Overall MRD-negative CR with a sensitivity of at least 10-5
Time to subsequent antimyeloma therapy
PFS on next-line therapy (PFS2)
Incidence, severity, and type of AEs, clinical laboratory results, and other safety parameters
OS
PK and pharmacodynamic markers by protein, DNA, or RNA analyses, including but not limited to, systemic

inflammatory cytokine concentrations, markers of CAR-T cell expansion (proliferation) and persistence via monitoring of cilta-cel-positive cellular concentrations, and cilta-cel transgene levels
Mean change from baseline in the EORTC-QLQ-C30, MySIm-Q, and EQ-5D-5L subscale scores and the PROCTCAE items
Time to improvement or worsening of symptoms, functioning, and overall well-being
Improvement or worsening in the EORTC-QLQ- C30 and MySIm-Q subscale scores using the PGIS to calculate the meaningful change threshold
Presence of RCL

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

18 years of age or older
Participants with documented NDMM according to IMWG diagnostic criteria, for whom high-dose therapy and ASCT are part of the intended initial treatment plan.
Measurable disease, as assessed by central laboratory, at screening as defined by any of the following: 1) Serum monoclonal paraprotein (M-protein) level 1.0 g/dL or urine M-protein level 200 mg/24 hours; or 2) Light chain MM without measurable disease in serum or urine: serum Ig free-light chain (FLC) 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio.
ECOG performance status of grade 0 or 1
Clinical laboratory values within prespecified range as listed in 5.1.1, page 55 of the protocol.

Criterios de Exclusión

Prior treatment with CAR-T therapy directed at any target.
Any prior BCMA target therapy.
Any prior therapy for MM or smoldering myeloma other than a short course of corticosteroids
Received a strong cytochrome P450 (CYP)3A4 inducer within 5 halflives prior to randomization
Received or plans to receive any live, attenuated vaccine (except for COVID-19 vaccines) within 4 weeks prior to randomization.
Known active, or prior history of central nervous system (CNS) involvement or clinical signs of meningeal involvement of MM
Stroke or seizure within 6 months of signing Informed Consent Form (ICF)

Calendario

(Última actualización: 17/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
03/11/2022	25/09/2023	10/10/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

European Myeloma Network B.V. Netherlands

Blaak 555

Contact Person

Pieter Sonneveld

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (06/10/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Hematologia

Activo (10/02/2024)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Activo (12/12/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Hematología

Activo (06/10/2023)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Activo (26/02/2024)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Hematología

Activo (01/02/2024)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Hematología

Activo (12/02/2024)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología

Activo (20/02/2024)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Hematología

Activo (02/11/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

No iniciado (--/--/----)

Institut Catala D´oncologia

Badalona

BARCELONA

Z97ES10008: Hematología

Activo (05/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

Activo (11/12/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematologia

Medicamentos

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01XL05 - CILTACABTAGEN AUTOLEUCEL
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

Dexamethason Teva 4 mg, tabletten
TABLET
ORAL USE

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

Experimental

Lenalidomide Accord 2.5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01FC01 - DARATUMUMAB
Principios Activos: N/A

Huérfano
Experimental

Dexamethasone 2mg Tablets
TABLET
ORAL USE

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

Experimental

Lenalidomide Accord 25 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Lenalidomide Accord 20 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Sin resultados

A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	366
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics	Gene therapy

Information

Identifier
2023-507632-20-00 (CTIS)

Protocol Code
EMN2868284528MMY3005

Transitioned 2021-003284-10

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Multiple Myeloma

Scientific Title

A Phase 3 Randomized Study Comparing Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Ciltacabtagene Autoleucel versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible

Rationale

Not provided

Main Objective

To compare the efficacy of DVRd followed by cilta-cel and lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy in terms of PFS and sustained MRD-negative CR

Primary Endpoints

PFS
Sustained MRD-negative CR, defined as MRD-negative CR for at a minimum 12 months duration, with MRD status determined by NGS with a sensitivity of at least 10-5

Temporary moments of secondary assessment

Not provided

Secondary Objective

To further compare the efficacy of DVRd followed by cilta-cel and lenalidomide therapy
To characterize the safety of cilta-cel after DVRd therapy followed by lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy
To characterize the PK and pharmacodynamics of cilta-cel
To evaluate the PRO associated with DVRd followed by cilta-cel and lenalidomide therapy versus DVRd followed by ASCT, DVRd consolidation, and lenalidomide therapy
To determine whether RCL is present in participants that receive ciltacel

Secondary Endpoints

Overall response (PR or better) status and CR or better status
Overall MRD-negative CR with a sensitivity of at least 10-5
Time to subsequent antimyeloma therapy
PFS on next-line therapy (PFS2)
Incidence, severity, and type of AEs, clinical laboratory results, and other safety parameters
OS
PK and pharmacodynamic markers by protein, DNA, or RNA analyses, including but not limited to, systemic

inflammatory cytokine concentrations, markers of CAR-T cell expansion (proliferation) and persistence via monitoring of cilta-cel-positive cellular concentrations, and cilta-cel transgene levels
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Time to improvement or worsening of symptoms, functioning, and overall well-being
Improvement or worsening in the EORTC-QLQ- C30 and MySIm-Q subscale scores using the PGIS to calculate the meaningful change threshold
Presence of RCL

Temporary moments of secondary assessment

Not provided

Inclusion criteria

18 years of age or older
Participants with documented NDMM according to IMWG diagnostic criteria, for whom high-dose therapy and ASCT are part of the intended initial treatment plan.
Measurable disease, as assessed by central laboratory, at screening as defined by any of the following: 1) Serum monoclonal paraprotein (M-protein) level 1.0 g/dL or urine M-protein level 200 mg/24 hours; or 2) Light chain MM without measurable disease in serum or urine: serum Ig free-light chain (FLC) 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio.
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Received a strong cytochrome P450 (CYP)3A4 inducer within 5 halflives prior to randomization
Received or plans to receive any live, attenuated vaccine (except for COVID-19 vaccines) within 4 weeks prior to randomization.
Known active, or prior history of central nervous system (CNS) involvement or clinical signs of meningeal involvement of MM
Stroke or seizure within 6 months of signing Informed Consent Form (ICF)

Calendar

(Last Update: 17/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
03/11/2022	25/09/2023	10/10/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

European Myeloma Network B.V. Netherlands

Blaak 555

Contact Person

Pieter Sonneveld

+31102687065

p.sonneveld@erasmusmc.nl

Monetary support: N/A

Sponsor type: Commercial

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917792613

Sites

Active (06/10/2023)

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NAVARRA

Hematologia

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HOSPITAL UNIVERSITARIO RAMON Y CAJAL

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Hematología

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HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología

Active (20/02/2024)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Hematología

Active (02/11/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

not initialized (--/--/----)

Institut Catala D´oncologia

Badalona

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Z97ES10008: Hematología

Active (05/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

Active (11/12/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematologia

Medication

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

ATC code: L01XL05 - CILTACABTAGEN AUTOLEUCEL
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

Dexamethason Teva 4 mg, tabletten
TABLET
ORAL USE

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

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Lenalidomide Accord 2.5 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

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DARZALEX 1800 mg solution for injection
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Active Principles: N/A

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Experimental

Dexamethasone 2mg Tablets
TABLET
ORAL USE

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

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Lenalidomide Accord 25 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L04AX04 - LENALIDOMIDA

Active Principles: N/A

Experimental

Lenalidomide Accord 20 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L04AX04 - LENALIDOMIDA

Active Principles: N/A

Experimental

No results