Trial of an investigational drug after the rejection of an allogeneic transplant.

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	25
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico nacional	seguridad, dosis	Terapia celular

Información

Identificador
2022-503063-15-00 (CTIS)

Cod. Protocolo
CARTemis-1

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

Enfermedad investigada
Multiple myeloma.

Título Científico
Anti-BCMA chimeric antigen receptor (CARTemis-1) T-lymphocyte therapy in the treatment of patients with multiple myeloma in relapse after allogeneic transplant: EGFR expression as a control mechanism of treatment-derived complications

Justificación

No aportado

Objetivo Principal

Assess the feasibility of generating HUVR-CARTemis-1 and its safety in terms of maximum tolerated dose in patients with multiple myeloma in 1st or successive relapses after allogeneic transplant.

Variables de Evaluación Primaria

Primary feasibility variable: Number of cases in which the manufacturing process is completed and HUVR-CARTemis-1 cells are infused.
Safety variables: Maximum tolerated dose of HUVR-CARTemis-1 determined based on the incidence in different patient cohorts of the following toxicities: Rate of patients developing cytokine release syndrome and/or neurological toxicity and/or macrophage activation. Rate of patients developing graft-versus-recipient disease - Patients developing grade 3-4 toxicities that do not respond to standard treatment. Presence of infusional reactions. - Presence of SAEs, SUSARs throughout the study.
Safety variables: Tumour lysis syndrome.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Evaluate the response at 3, 6 and 12 months after the administration of HUVR-CARTemis-1, evaluate the duration of the response, assess overall and event-free survival after administration of HUVR-CARTemis-1, analyze the biological characteristics of the HUVR-CARTemis-1 cells generated and infused, evaluate the persistence of HUVR-CARTemis-1 cells in peripheral blood after administration.

Variables de Evaluación Secundaria

Determine cytopenias developed during the first 90 days or prolonged
Duration of response in responder patients
Overall response rate
Time to complete remission
Time to best response
Rate of bone marrow-negative EMR
Extramedullary disease response rate
Progression-free survival
HUVR-CARTemis-1 administration and disease progression or death
Overall survival and patient death
Persistence of HUVR-CARTemis-1 in peripheral blood and marrow

Evaluation of the biological characteristics of HUVR-CARTemis-1
BCMA expression
Levels of soluble BCMA

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Patients > 18 years old with a diagnosis of post-allogeneic transplant relapse multiple myeloma. 2. Medical illness 3. Previous treatment with 2 lines before and/or after allogeneic transplant. 4. Patients who are not receiving immunosuppressants at least 1 month before inclusion and who do not have active GVHD. 5. ECOG functional status from 0 to 1. 6. Life expectancy greater than 3 months 7. Patients who give their consent by signing the Informed Consent document.

Criterios de Exclusión

1. Active systemic immunosuppressive therapy. 2. Patients who have previously received CAR-T Anti-BCMA treatment. Patients who have received another type of anti-BCMA therapy will not be excluded, although in this case the positivity for BCMA in myeloma cells must be confirmed at the time of inclusion. 3. Absolute lymphocyte count <0.2x109/L. 4. Previous malignancy, except if in complete remission >3 years, with the exception of cutaneous carcinoma (non-melanoma). 5. Active infection requiring treatment. 6. Active HIV, HBV, or HCV infection. 7. Uncontrolled medical illness. 8. Severe organic disease that meets any of the following criteria: EF <40%, DLCO < 40%, GFR < 50 ml/min, bilirubin > 3 NV (except Gilbert's syndrome). 9. Previous diagnosis of symptomatic AL amyloidosis or POEMS syndrome. 10. Pregnant or lactating women. 11. Women of childbearing potential who are unable or unwilling to use highly effective contraceptive methods 12. Men unable or unwilling to use highly effective contraceptive methods 13. Contraindication to receive lymphodepletive chemotherapy.

Calendario

(Última actualización: 27/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
06/05/2024	22/09/2025	30/09/2025	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

Fundacion Publica Andaluza para la Gestion de la Investigacion en Salud de Sevilla (FISEVI) Spain

Avenida De Manuel Siurot S/n

Contact Person

Unidad de Investigación Clínica y Ensayos Clínicos del Hospital Universitario Virgen del Rocío

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Monetary support: N/A

Tipo de promotor: No comercial

Ceim

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955043127

Centros

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology & Hemotherapy

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology & Hemotherapy

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology & Hemotherapy

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology & Hemotherapy

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology & Hemotherapy

Medicamentos

ALLOPURINOL
TABLET
ORAL

-
Principios Activos: N/A

Experimental

TOCILIZUMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

PRD11110761
DISPERSION FOR INFUSION
INFUSION

-
Principios Activos: N/A

Experimental

FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

PARACETAMOL
INTRAVENOUS INFUSION
ORAL AND IV

-
Principios Activos: N/A

Experimental

CETUXIMAB
SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

DEXCHLORPHENIRAMINE
SOLUTION FOR INJECTION
ORAL AND IV

-
Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

Sin resultados

Trial of an investigational drug after the rejection of an allogeneic transplant.

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	25
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
National multicenter	safety, dose	Cellular therapy

Information

Identifier
2022-503063-15-00 (CTIS)

Protocol Code
CARTemis-1

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

Investigated Disease
Multiple myeloma.

Scientific Title
Anti-BCMA chimeric antigen receptor (CARTemis-1) T-lymphocyte therapy in the treatment of patients with multiple myeloma in relapse after allogeneic transplant: EGFR expression as a control mechanism of treatment-derived complications

Rationale

Not provided

Main Objective

Assess the feasibility of generating HUVR-CARTemis-1 and its safety in terms of maximum tolerated dose in patients with multiple myeloma in 1st or successive relapses after allogeneic transplant.

Primary Endpoints

Primary feasibility variable: Number of cases in which the manufacturing process is completed and HUVR-CARTemis-1 cells are infused.
Safety variables: Maximum tolerated dose of HUVR-CARTemis-1 determined based on the incidence in different patient cohorts of the following toxicities: Rate of patients developing cytokine release syndrome and/or neurological toxicity and/or macrophage activation. Rate of patients developing graft-versus-recipient disease - Patients developing grade 3-4 toxicities that do not respond to standard treatment. Presence of infusional reactions. - Presence of SAEs, SUSARs throughout the study.
Safety variables: Tumour lysis syndrome.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Evaluate the response at 3, 6 and 12 months after the administration of HUVR-CARTemis-1, evaluate the duration of the response, assess overall and event-free survival after administration of HUVR-CARTemis-1, analyze the biological characteristics of the HUVR-CARTemis-1 cells generated and infused, evaluate the persistence of HUVR-CARTemis-1 cells in peripheral blood after administration.

Secondary Endpoints

Determine cytopenias developed during the first 90 days or prolonged
Duration of response in responder patients
Overall response rate
Time to complete remission
Time to best response
Rate of bone marrow-negative EMR
Extramedullary disease response rate
Progression-free survival
HUVR-CARTemis-1 administration and disease progression or death
Overall survival and patient death
Persistence of HUVR-CARTemis-1 in peripheral blood and marrow

Evaluation of the biological characteristics of HUVR-CARTemis-1
BCMA expression
Levels of soluble BCMA

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Patients > 18 years old with a diagnosis of post-allogeneic transplant relapse multiple myeloma. 2. Medical illness 3. Previous treatment with 2 lines before and/or after allogeneic transplant. 4. Patients who are not receiving immunosuppressants at least 1 month before inclusion and who do not have active GVHD. 5. ECOG functional status from 0 to 1. 6. Life expectancy greater than 3 months 7. Patients who give their consent by signing the Informed Consent document.

Exclusion criteria

1. Active systemic immunosuppressive therapy. 2. Patients who have previously received CAR-T Anti-BCMA treatment. Patients who have received another type of anti-BCMA therapy will not be excluded, although in this case the positivity for BCMA in myeloma cells must be confirmed at the time of inclusion. 3. Absolute lymphocyte count <0.2x109/L. 4. Previous malignancy, except if in complete remission >3 years, with the exception of cutaneous carcinoma (non-melanoma). 5. Active infection requiring treatment. 6. Active HIV, HBV, or HCV infection. 7. Uncontrolled medical illness. 8. Severe organic disease that meets any of the following criteria: EF <40%, DLCO < 40%, GFR < 50 ml/min, bilirubin > 3 NV (except Gilbert's syndrome). 9. Previous diagnosis of symptomatic AL amyloidosis or POEMS syndrome. 10. Pregnant or lactating women. 11. Women of childbearing potential who are unable or unwilling to use highly effective contraceptive methods 12. Men unable or unwilling to use highly effective contraceptive methods 13. Contraindication to receive lymphodepletive chemotherapy.

Calendar

(Last Update: 27/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
06/05/2024	22/09/2025	30/09/2025	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

Fundacion Publica Andaluza para la Gestion de la Investigacion en Salud de Sevilla (FISEVI) Spain

Avenida De Manuel Siurot S/n

Contact Person

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Monetary support: N/A

Sponsor type: No commercial

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Sites

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology & Hemotherapy

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology & Hemotherapy

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology & Hemotherapy

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology & Hemotherapy

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology & Hemotherapy

Medication

ALLOPURINOL
TABLET
ORAL

-

Active Principles: N/A

Experimental

TOCILIZUMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

PRD11110761
DISPERSION FOR INFUSION
INFUSION

-

Active Principles: N/A

Experimental

FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

PARACETAMOL
INTRAVENOUS INFUSION
ORAL AND IV

-

Active Principles: N/A

Experimental

CETUXIMAB
SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

DEXCHLORPHENIRAMINE
SOLUTION FOR INJECTION
ORAL AND IV

-

Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

No results