

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

Estado
Reclutando

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase I , Fase II

Participantes esperados
25

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
Si

Cobertura geográfica
Multicéntrico nacional

Ámbitos del ensayo
seguridad, dosis

Terapia avanzada
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 06/05/2024	Inicio de Ensayo 22/09/2025	Inclusión Primer Paciente 30/09/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 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

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Monetary support: N/A

Tipo de promotor: No comercial

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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

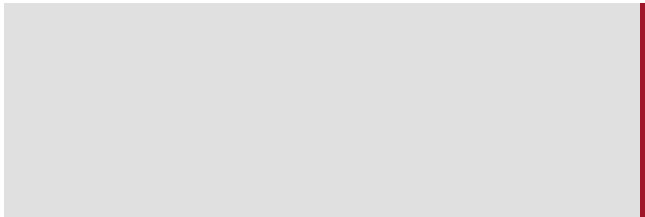
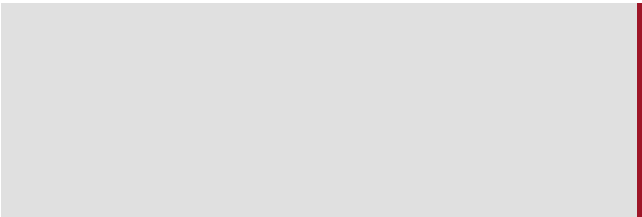
CYCLOPHOSPHAMIDE

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
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase I , Phase II

Expected Participants
25

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
National multicenter

Areas of the study
safety, dose

Advanced therapy
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

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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 06/05/2024	Start of Trial 22/09/2025	First patient inclusion 30/09/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) 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

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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

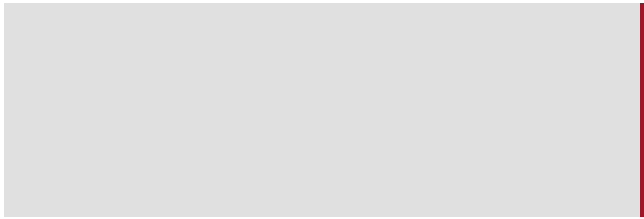
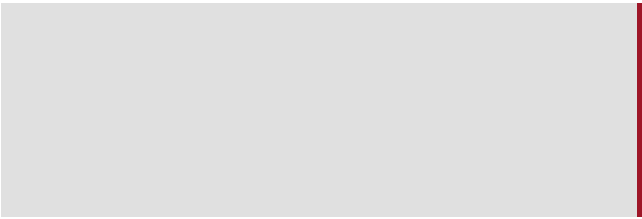
Experimental

CYCLOPHOSPHAMIDE

POWDER FOR SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS

Active Principles: N/A

Experimental



No results