Single-center phase I/IIa study with CART cells produced using the anti-CD19 transposon technique (TranspoCART19) for patients with CD19+ acute lymphoblastic leukemia resistant or refractory to treatment

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	24
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	eficacia, dosis	NO

Información

Identificador
2025-522673-11-00 (CTIS)

Cod. Protocolo
Transpocall19

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

Enfermedad investigada
refractory or resistant CD19+ acute lymphoblastic leukemia

Título Científico
Single-center phase I/IIa study of infusion of autologous peripheral blood T cells expanded and genetically modified by Sleeping Beauty family transposons to express a chimeric antigen receptor with anti-CD19 specificity conjugated with the 4-1BB costimulatory region and CD3z and huEGFRt signal transmission (TranspoCART19) in patients with

CD19+ acute lymphoblastic leukemia resistant or refractory to treatment

Justificación

No aportado

Objetivo Principal

Phase 1:
To determine the maximum tolerated dose (MTD) and/or recommended dose of TranspoCART19 cells in patients with treatment-resistant or refractory CD19+ acute lymphoblastic leukemia.
Phase 2:
To evaluate the efficacy of TranspoCART19 cell infusion in patients with treatment-resistant or refractory CD19+ acute lymphoblastic leukemia.

Variables de Evaluación Primaria

To determine the maximum tolerated dose and evaluate the safety of TranspoCART19 cell infusion.
To determine the efficacy of TranspoCART19 cell infusion

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate adverse events occurring after TranspoCART19 cell infusion at three months and one year.
To evaluate overall and progression-free survival after TranspoCART19 infusion.
To evaluate the duration of response after TranspoCART19 infusion.
To evaluate the expansion and persistence of TranspoCART19 cells in peripheral blood after administration.
To evaluate the effect of treatment with TranspoCART19 on the quality of life of patients

Variables de Evaluación Secundaria

Toxicity assessment at 3 months and 1 year, defined as the number of grade II-IV adverse events using the CTC (Common Toxicity Criteria) version 5.0 (Annex 4) and the ASTCT classification.
Treatment-related mortality (TRM) at 1, 3, and 1 year, defined as any death not directly caused by leukemia. For the purpose of estimating TRM, disease relapse or progression will be considered a competing event.
Progression-free survival (PFS) at six months and one year after the procedure, defined as the time between TranspoCART19 infusion and disease progression or death. Patients alive and in complete remission will be censored at the time of last follow-up.
Overall survival (OS) at one year after infusion, defined as the time between TranspoCART19 infusion and the patient's death from any cause. Surviving patients will be censored at the time of last follow-up.

Response rate (overall and complete) at three months and one year.
Best response rate achieved during the first 3 months of follow-up after administration of the first fraction of TranspoCART19.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Diagnosis of CD19+ acute lymphoblastic leukemia, with a prognosis of less than 2 years due to meeting one of the following conditions: Relapsed/refractory, not a transplant candidate (due to refractory disease or lack of a donor) Relapse after allogeneic transplant
Measurable disease, understood as the presence of at least residual measurable disease by flow cytometry in bone marrow or peripheral blood at the time of inclusion.
Age over 4 years and under 70 years.
ECOG performance status 0-1. Patients with ECOG 2 may be included if due to hematologic disease (Appendix 1).
Life expectancy greater than 3 months.
Adequate venous access for lymphapheresis. No contraindications.
Signing of informed consent (patient or legal guardian).

Criterios de Exclusión

Patients who, in the opinion of their physician, may benefit from other approved, potentially curative therapeutic options, including commercial CAR-T cells. HIV infecction Concurrent and uncontrolled medical conditions including cardiac, renal, hepatic, gastrointestinal, endocrine, pulmonary, neurological, or psychiatric conditions that, in the opinion of the investigator, pose a risk to the patient. Positive serology for hepatitis B, defined as a positive test for HBsAg. Additionally, if the patient is HBsAg negative but has anti-HBc antibodies, a hepatitis B virus DNA test will be required. If the result is positive, the patient will be excluded. Positive serology for hepatitis C, defined as a positive test for anti-HCV antibodies confirmed by RIBA. Severe organ involvement, defined as cardiac ejection fraction <40%; DLCO <40%; estimated glomerular filtration rate <30 ml/min; bilirubin >3 times the upper limit of normal (unless due to Gilbert's syndrome). Pregnant or breastfeeding women. Women of childbearing age must have a negative pregnancy test during the screening phase. Women of childbearing potential, including those whose last menstrual cycle was in the year prior to screening, who are unable or unwilling to use highly effective contraception* from baseline to completion. Men who are unable or unwilling to use highly effective contraception* from the start of the study until its completion. Treatment with any experimental or non-marketed substance within four weeks prior to enrollment, or actively participating in another therapeutic clinical trial. Previous treatment with CART (commercial or experimental). Diagnosis of another malignancy, past or present. Patients who have been in complete remission for more than 3 years, or with a history of non-melanoma skin cancer or completely resected carcinoma in situ, may be included. Overt central nervous system involvement (CNS-3) at the time of inclusion. Patients with a lesser degree (CNS-2) or CNS-3 who have responded to intrathecal chemotherapy will be eligible for inclusion. Isolated extramedullary involvement (i.e., in the absence of residual measurable disease in peripheral blood or bone marrow). In the case of relapse after allogeneic transplantation, at least 3 months must have passed since the transplant for inclusion. Furthermore, the patient must have been off systemic immunosuppressants for at least 30 days to be eligible for inclusion. Active immunosuppressive therapy for graft-versus-host disease and other conditions. The use of corticosteroids for leukemia control should be limited as much as possible at the time of enrollment and should be discontinued before the infusion of TranspoCART19 cells. Active infection requiring systemic medical treatment.

Calendario

(Última actualización: 02/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
02/01/2026	17/03/2026	30/03/2026	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

Clinica Universidad De Navarra Spain

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Contact Person

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Monetary support: N/A

Tipo de promotor: No comercial

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Centros

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematología y hemoteriapia

Medicamentos

TranspoCART19

CELL SUSPENSION FOR INFUSION

INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

Single-center phase I/IIa study with CART cells produced using the anti-CD19 transposon technique (TranspoCART19) for patients with CD19+ acute lymphoblastic leukemia resistant or refractory to treatment

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	24
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	effectiveness, dose	NO

Information

Identifier
2025-522673-11-00 (CTIS)

Protocol Code
Transpocall19

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

Investigated Disease
refractory or resistant CD19+ acute lymphoblastic leukemia

Scientific Title
Single-center phase I/IIa study of infusion of autologous peripheral blood T cells expanded and genetically modified by Sleeping Beauty family transposons to express a chimeric antigen receptor with anti-CD19 specificity conjugated with the 4-1BB costimulatory region and CD3z and huEGFRt signal transmission (TranspoCART19) in patients with

CD19+ acute lymphoblastic leukemia resistant or refractory to treatment

Rationale

Not provided

Main Objective

Phase 1:
To determine the maximum tolerated dose (MTD) and/or recommended dose of TranspoCART19 cells in patients with treatment-resistant or refractory CD19+ acute lymphoblastic leukemia.
Phase 2:
To evaluate the efficacy of TranspoCART19 cell infusion in patients with treatment-resistant or refractory CD19+ acute lymphoblastic leukemia.

Primary Endpoints

To determine the maximum tolerated dose and evaluate the safety of TranspoCART19 cell infusion.
To determine the efficacy of TranspoCART19 cell infusion

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate adverse events occurring after TranspoCART19 cell infusion at three months and one year.
To evaluate overall and progression-free survival after TranspoCART19 infusion.
To evaluate the duration of response after TranspoCART19 infusion.
To evaluate the expansion and persistence of TranspoCART19 cells in peripheral blood after administration.
To evaluate the effect of treatment with TranspoCART19 on the quality of life of patients

Secondary Endpoints

Toxicity assessment at 3 months and 1 year, defined as the number of grade II-IV adverse events using the CTC (Common Toxicity Criteria) version 5.0 (Annex 4) and the ASTCT classification.
Treatment-related mortality (TRM) at 1, 3, and 1 year, defined as any death not directly caused by leukemia. For the purpose of estimating TRM, disease relapse or progression will be considered a competing event.
Progression-free survival (PFS) at six months and one year after the procedure, defined as the time between TranspoCART19 infusion and disease progression or death. Patients alive and in complete remission will be censored at the time of last follow-up.
Overall survival (OS) at one year after infusion, defined as the time between TranspoCART19 infusion and the patient's death from any cause. Surviving patients will be censored at the time of last follow-up.

Response rate (overall and complete) at three months and one year.
Best response rate achieved during the first 3 months of follow-up after administration of the first fraction of TranspoCART19.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Diagnosis of CD19+ acute lymphoblastic leukemia, with a prognosis of less than 2 years due to meeting one of the following conditions: Relapsed/refractory, not a transplant candidate (due to refractory disease or lack of a donor) Relapse after allogeneic transplant
Measurable disease, understood as the presence of at least residual measurable disease by flow cytometry in bone marrow or peripheral blood at the time of inclusion.
Age over 4 years and under 70 years.
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Life expectancy greater than 3 months.
Adequate venous access for lymphapheresis. No contraindications.
Signing of informed consent (patient or legal guardian).

Exclusion criteria

Patients who, in the opinion of their physician, may benefit from other approved, potentially curative therapeutic options, including commercial CAR-T cells. HIV infecction Concurrent and uncontrolled medical conditions including cardiac, renal, hepatic, gastrointestinal, endocrine, pulmonary, neurological, or psychiatric conditions that, in the opinion of the investigator, pose a risk to the patient. Positive serology for hepatitis B, defined as a positive test for HBsAg. Additionally, if the patient is HBsAg negative but has anti-HBc antibodies, a hepatitis B virus DNA test will be required. If the result is positive, the patient will be excluded. Positive serology for hepatitis C, defined as a positive test for anti-HCV antibodies confirmed by RIBA. Severe organ involvement, defined as cardiac ejection fraction <40%; DLCO <40%; estimated glomerular filtration rate <30 ml/min; bilirubin >3 times the upper limit of normal (unless due to Gilbert's syndrome). Pregnant or breastfeeding women. Women of childbearing age must have a negative pregnancy test during the screening phase. Women of childbearing potential, including those whose last menstrual cycle was in the year prior to screening, who are unable or unwilling to use highly effective contraception* from baseline to completion. Men who are unable or unwilling to use highly effective contraception* from the start of the study until its completion. Treatment with any experimental or non-marketed substance within four weeks prior to enrollment, or actively participating in another therapeutic clinical trial. Previous treatment with CART (commercial or experimental). Diagnosis of another malignancy, past or present. Patients who have been in complete remission for more than 3 years, or with a history of non-melanoma skin cancer or completely resected carcinoma in situ, may be included. Overt central nervous system involvement (CNS-3) at the time of inclusion. Patients with a lesser degree (CNS-2) or CNS-3 who have responded to intrathecal chemotherapy will be eligible for inclusion. Isolated extramedullary involvement (i.e., in the absence of residual measurable disease in peripheral blood or bone marrow). In the case of relapse after allogeneic transplantation, at least 3 months must have passed since the transplant for inclusion. Furthermore, the patient must have been off systemic immunosuppressants for at least 30 days to be eligible for inclusion. Active immunosuppressive therapy for graft-versus-host disease and other conditions. The use of corticosteroids for leukemia control should be limited as much as possible at the time of enrollment and should be discontinued before the infusion of TranspoCART19 cells. Active infection requiring systemic medical treatment.

Calendar

(Last Update: 02/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
02/01/2026	17/03/2026	30/03/2026	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

Clinica Universidad De Navarra Spain

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Contact Person

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Monetary support: N/A

Sponsor type: No commercial

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Sites

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematología y hemoteriapia

Medication

TranspoCART19
CELL SUSPENSION FOR INFUSION
INFUSION

-

Active Principles: N/A

Experimental

No results