Safety and efficacy of hCD1a-CAR T (OC-1) therapy, in patients with relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	20
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	Terapia génica

Información

Identificador

2024-514591-40-00 (CTIS)

Cod. Protocolo

OC-01-21001- CARxALL

Transicionado 2021-002333-42

Área terapéutica

Enfermedades [C] - Hematología [C15]|

Enfermedad investigada

T-cell Acute Lymphoblastic Leukemia
T-cell acute lymphoblastic Lymphoma

Título Científico

Safety and efficacy of hCD1a-CAR T (OC-1) therapy, in patients with relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)_CARxALL

Justificación

No aportado

Objetivo Principal

To assess the safety of OC-1 in patients with primary relapsed/refractory CD1a-positive T-ALL/LL.

Variables de Evaluación Primaria

Number of adverse events grade III-IV using Common Toxicity Criteria for Adverse Events (CTCAE) version 5.
Incidence of severe Cytokine release syndrome (CRS) # grade III and Immune effector cell-associated neurotoxicity syndrome (ICANS) # grade II
Proportion of patients with non-relapse, treatment-related mortality (NRM)
Number of adverse events of special interest (AESI)
Assessment of the immunological homeostasis, through the description of lymphocytes subpopulations at each study timepoint.
Incidence of severe (#3) treatment-related dermatological events.
Number of patients developing dose limiting toxicity (DLT)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To describe the response to OC-1.
To describe the duration of the response after the administration of OC-1.
To describe the overall survival after the administration of OC-1
To describe the persistence of OC-1 cells in peripheral blood after administration

Variables de Evaluación Secundaria

Remission rate: Percentage of patients presenting complete response (CR) or incomplete count recovery (CRi) at any point after treatment
Duration of remission: The duration of the remission will be assessed from the first documented date of remission status until progression (in days)
Minimal residual disease (MRD) response by flow cytometry: blast count among patients presenting bone marrow complete response (sensitivity 10-4).
Progression-free survival: time since the first infusion to the documented loss of response. In patients not presenting

a CR or CRi progression free survival will be zero
Overall survival time since first infusion to date of death
Persistence of OC-1, as determined by flow cytometry and quantitative analysis by qPCR

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Children older than 2 years or adults, male and female in both groups.
Patients CD1a antigen blast expression 20% at inclusion, either immunophenotypically (flow cytometry) or histologically confirmed.
R/R CD1a-positive T-ALL/LL patients, including morphologic or MRD-detectable (1x10-4) bone marrow and/or extramedullary relapses after 2 therapy lines: Relapse after allogeneic haematopoietic stem cell transplantation (allo-HSCT) Primary refractoriness, defined as either morphologic persistence or detectable MRD (1x10-4) after two standard therapy lines, making the patient not candidate for allo-HSCT. Refractory first relapse. Second or further relapse.
Patient without reproductive capacity or else, commitment to the use of a highly effective method of contraception during the study.

Criterios de Exclusión

Limiting organ dysfunction, such as uncontrolled cardiac (e.g., depressed left ventricular ejection fraction (LVEF), <45%), pulmonary, liver, renal or CNS dysfunction. Other non-controlled concomitant neoplasms. Allo-HSCT within a time frame <3 months, or requiring continued immunosuppressive treatment for graft versus host disease (GvHD). Uncontrolled epilepsy or underlying central nervous system (CNS) severe disease. Active bacterial, fungal or viral infection not controlled by adequate treatment. Known HIV, active hepatitis B (HBV), or hepatitis C virus (HCV) infection. Women who are pregnant (urine/blood pregnancy test positive) or lactating. Severe illness or medical condition, which would not permit the patient to be managed according to the protocol. Suffering from a serious autoimmune disease or immunodeficiency disease The patient participated in other experimental drug clinical trial within 6 weeks prior to OC-1 infusion.

Calendario

(Última actualización: 15/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
25/11/2022	31/01/2023	07/02/2023	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

Onechain Immunotherapeutics S.L. Spain

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (06/02/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (31/01/2023)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Medicamentos

hCD1a-CAR T

SUSPENSION FOR IV INFUSION

INTRAVASCULAR USE

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

Safety and efficacy of hCD1a-CAR T (OC-1) therapy, in patients with relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months)
Gender	**Phases**	**Expected Participants**
Both	Phase I	20
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	Gene therapy

Information

Identifier
2024-514591-40-00 (CTIS)

Protocol Code
OC-01-21001- CARxALL

Transitioned 2021-002333-42

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

Investigated Disease
T-cell Acute Lymphoblastic Leukemia
T-cell acute lymphoblastic Lymphoma

Scientific Title

Safety and efficacy of hCD1a-CAR T (OC-1) therapy, in patients with relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)_CARxALL

Rationale

Not provided

Main Objective

To assess the safety of OC-1 in patients with primary relapsed/refractory CD1a-positive T-ALL/LL.

Primary Endpoints

Number of adverse events grade III-IV using Common Toxicity Criteria for Adverse Events (CTCAE) version 5.
Incidence of severe Cytokine release syndrome (CRS) # grade III and Immune effector cell-associated neurotoxicity syndrome (ICANS) # grade II
Proportion of patients with non-relapse, treatment-related mortality (NRM)
Number of adverse events of special interest (AESI)
Assessment of the immunological homeostasis, through the description of lymphocytes subpopulations at each study timepoint.
Incidence of severe (#3) treatment-related dermatological events.
Number of patients developing dose limiting toxicity (DLT)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To describe the response to OC-1.
To describe the duration of the response after the administration of OC-1.
To describe the overall survival after the administration of OC-1
To describe the persistence of OC-1 cells in peripheral blood after administration

Secondary Endpoints

Remission rate: Percentage of patients presenting complete response (CR) or incomplete count recovery (CRi) at any point after treatment
Duration of remission: The duration of the remission will be assessed from the first documented date of remission status until progression (in days)
Minimal residual disease (MRD) response by flow cytometry: blast count among patients presenting bone marrow complete response (sensitivity 10-4).
Progression-free survival: time since the first infusion to the documented loss of response. In patients not presenting

a CR or CRi progression free survival will be zero
Overall survival time since first infusion to date of death
Persistence of OC-1, as determined by flow cytometry and quantitative analysis by qPCR

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Children older than 2 years or adults, male and female in both groups.
Patients CD1a antigen blast expression 20% at inclusion, either immunophenotypically (flow cytometry) or histologically confirmed.
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Exclusion criteria

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Calendar

(Last Update: 15/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
25/11/2022	31/01/2023	07/02/2023	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

Onechain Immunotherapeutics S.L. Spain

Carrer De Muntaner 383 3rd-2nd

Contact Person

Medical Department

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administracion@onechaintx.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (06/02/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Active (31/01/2023)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Medication

hCD1a-CAR T

SUSPENSION FOR IV INFUSION

INTRAVASCULAR USE

-

Active Principles: N/A

Orphan **Experimental**

No results