Long-term Follow-up study for relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL) patients previously treated with OC-1 cells.

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) , Lactantes y preescolar (28 días - 23 meses)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	20
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad	NO

Información

Identificador
2024-516617-20-00 (CTIS)

Cod. Protocolo
OC-01-23002

Área terapéutica
·Enfermedades [C] - Hematología [C15]
·Enfermedades [C] - Cáncer [C04]

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

Título Científico
Long-term Follow-up study for relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)

patients previously treated with OC-1 cells.

Justificación

No aportado

Objetivo Principal

To monitor patients with primary relapsed/refractory (R/R) CD1a-positive T-ALL/LL who received OC-1 cells, for 15 years following CAR-T infusion to assess the risk of delayed adverse events (AEs).

Variables de Evaluación Primaria

Number of adverse events grade III-IV, related or possibly related, using Common Toxicity Criteria for Adverse Events (CTCAE) version 5
Proportion of patients with: - New malignancies. - Incidence/exacerbation of pre-existing neurologic disorder. - New incidence or exacerbation of a prior rheumatologic or other ATMP-CLINICAL TRIAL PROTOCOL OC-01-23002 EU CT Number: 2024-516617-20-00 Page 6 de 39 Protocol Version 1, 4 november 2024 autoimmune disorder. - New incidence of a hematologic disorder. - New incidence of infection (potentially product-related)- - New incidence of skin disorder

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the long-term efficacy of the product.
Monitor the persistence of OC-1 cells

Variables de Evaluación Secundaria

Overall survival following OC-1 cell therapy infusion
Progression-free survival
Progression-free survival in patients who did not received HSCT after OC-1 infusion
Proportion of patients who received an HSCT post OC-1 infusion
Persistence of OC-1, as determined by flow cytometry and quantitative analysis by qPCR. Genomic copy number integrations of the CAR in peripheral blood (PB) T cells and percentage of CD1a CAR-expressing T cells.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients previously treated with at least one fraction of OC-1 cell investigational product
Patient or patients legal representative has provided signed and dated informed consent.
Patient is able to comply with the study requirements.

Criterios de Exclusión

None. All patients who have received prior treatment with OC-1 cell investigational product are eligible for this long-term follow up (LTFU) study.

Calendario

(Última actualización: 20/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/04/2025	21/05/2025	07/07/2026	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

Onechain Immunotherapeutics S.L. Spain

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

Hematology

Medicamentos

hCD1a-CAR T
SUSPENSION FOR IV INFUSION
INTRAVASCULAR USE

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

Long-term Follow-up study for relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL) patients previously treated with OC-1 cells.

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) , Infants and preschool (28 days - 23 months)

Gender	Phases	Expected Participants
Both	Phase III	20

Results	Low level of intervention	Rare disease
No results	No	Yes

Geographic coverage	Areas of the study	Advanced therapy
Undetermined	safety	NO

Information

Identifier
2024-516617-20-00 (CTIS)

Protocol Code
OC-01-23002

Therapeutic area
·Diseases [C] - Hemic and Lymphatic Diseases [C15]
·Diseases [C] - Cancer [C04]

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

Scientific Title
Long-term Follow-up study for relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoma (T-ALL/LL)

patients previously treated with OC-1 cells.

Rationale

Not provided

Main Objective

To monitor patients with primary relapsed/refractory (R/R) CD1a-positive T-ALL/LL who received OC-1 cells, for 15 years following CAR-T infusion to assess the risk of delayed adverse events (AEs).

Primary Endpoints

Number of adverse events grade III-IV, related or possibly related, using Common Toxicity Criteria for Adverse Events (CTCAE) version 5
Proportion of patients with: - New malignancies. - Incidence/exacerbation of pre-existing neurologic disorder. - New incidence or exacerbation of a prior rheumatologic or other ATMP-CLINICAL TRIAL PROTOCOL OC-01-23002 EU CT Number: 2024-516617-20-00 Page 6 de 39 Protocol Version 1, 4 november 2024 autoimmune disorder. - New incidence of a hematologic disorder. - New incidence of infection (potentially product-related)- - New incidence of skin disorder

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the long-term efficacy of the product.
Monitor the persistence of OC-1 cells

Secondary Endpoints

Overall survival following OC-1 cell therapy infusion
Progression-free survival
Progression-free survival in patients who did not received HSCT after OC-1 infusion
Proportion of patients who received an HSCT post OC-1 infusion
Persistence of OC-1, as determined by flow cytometry and quantitative analysis by qPCR. Genomic copy number integrations of the CAR in peripheral blood (PB) T cells and percentage of CD1a CAR-expressing T cells.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients previously treated with at least one fraction of OC-1 cell investigational product
Patient or patients legal representative has provided signed and dated informed consent.
Patient is able to comply with the study requirements.

Exclusion criteria

None. All patients who have received prior treatment with OC-1 cell investigational product are eligible for this long-term follow up (LTFU) study.

Calendar

(Last Update: 20/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
11/04/2025	21/05/2025	07/07/2026	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

Onechain Immunotherapeutics S.L. Spain

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Contact Person

Medical Department

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

Hematology

Medication

hCD1a-CAR T
SUSPENSION FOR IV INFUSION
INTRAVASCULAR USE

-

Active Principles: N/A

Orphan **Experimental**

No results