Inmmunotherapy with peripheral blood, autologous, a dult T cells, expanded and transduced (gene modified) with a lentiviral vector expressing an anti-CD30-chimeric antigen receptor with 4-1-BB and CD3z costimulatory sequences in patients with Classical Hodgkin lymphoma and non-Hodgkin CD30+ T cell lymphoma.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	40
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	seguridad, eficacia	NO

Información

Identificador
2024-515624-36-00 (CTIS)

Cod. Protocolo
No aportado

Transicionado 2019-001263-70

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

Enfermedad investigada
Refractary or relapse non-Hodgkin T CD30+ lymphoma.
Refractary or relapse Hodgkin T CD30+ lymphoma

Título Científico

Inmmunotherapy with peripheral blood, autologous, a dult T cells, expanded and transduced (gene modified) with a lentiviral vector expressing an anti-CD30-chimeric antigen receptor with 4-1-BB and CD3z costimulatory sequences in patients with Classical Hodgkin lymphoma and non-Hodgkin CD30+ T cell lymphoma.

Justificación

No aportado

Objetivo Principal

To evaluate the safety and toxicity of HSP-CAR30 cell administration.

Variables de Evaluación Primaria

Dose-limiting toxicity (DLT): the proportion of patients with DLT in the first month after infusion of HSP-CAR30 cells will be calculated, for each dose, together with the 95% confidence interval.
Safety: Data on the type and frequency of AEs will be collected for each dose level, starting from the infusion of HSP-CAR30 cells and up to 30 days thereafter.
Answer: the percentage of responses (RC, RP and RG) will be analyzed according to RECIL 2017 criteria and its 95% confidence interval will be calculated. Only patients who receive the infusion of HSP-CAR30 cells will be evaluable for response. In no case will patients who do not present detectable disease by PET-CT (patient in CR), determined in the 30 days prior to the infusion of HSPCAR30 cells, be considered for response analysis.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

All patients must sign informed consent before the start of any procedure. General status according to ECOG scale: 0-1. FEV1 > 39%; DLCO and FVC > 39% of normal theoretical values. Absence of significant ventricular dysfunction: left ventricular ejection fraction >40%. Total bilirubin and transaminases < 3 times the maximum normal value, unless attributable to lymphoma. Creatinine < 2 times the maximum normal value and clearance > 40 mL/min. Negative serology for HIV, HBV and HCV. In the case of patients with positive serology for HBV or HCV, they must have a viral load of 0 measured by quantitative PCR Absence of active, clinically relevant bacterial or viral infection. A diagnostic test for influenza virus, respiratory syncytial (nasopharyngeal aspirate) and SarsCov2 must be performed in ALL patients, prior to starting treatment, with a negative result. All patients must have measurable disease (detected by PET-CT) at the time of inclusion. Patients with classic Hodgkin's disease: 1. Age 18-80 years or older Patients with classic Hodgkin's disease: 2. Patients in relapse after an autologous transplant of hemopoietic progenitors and who have previously received brentuximab vedotin and anti-PDL1 antibodies in any of the rescue treatments, without achieving CR. Patients with classic Hodgkin's disease: 3. Primary refractory patients (after 1st line of treatment) and who do not achieve CR after rescue treatments that include brentuximab and anti-PDL1 antibodies. Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 1. CD30 expression (determined by immunohistochemistry) in > 90% of tumor cells for peripheral T lymphoma Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 2. Age 18 years or older Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 3. Patients in relapse after an autologous transplant of hemopoietic progenitors. Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 4. Primary refractory patients (after 1st line of treatment that includes anthracycline) who do not achieve CR after rescue chemotherapy (type ESHAP, ICE, DHAP, Gemox or brentuximab vedotin).

Criterios de Exclusión

General condition determined according to ECOG scale: 2-4. Presence of cirrhosis or active hepatitis due to HBV or HCV virus Patients with concomitant severe neurological or psychiatric illness Presence of active autoimmune or rheumatologic disease requiring systemic treatment with any immunosuppressant (including prednisone at any dose). Pneumopathy of any type that causes a DLC <39% Major surgery in the 6 weeks prior to the start of inclusion. Any concomitant antineoplastic treatment. Pregnant or lactating patients. Previous or concurrent neoplasms. Except: basal cell or squamous cell carcinoma, history of carcinoma in situ with previous curative treatment, solid neoplasia with complete resection and in remission for >3 years. Before starting lymphoapheresis, all of the following requirements must be met: - absolute lymphocyte count in peripheral blood > 100/ml. - absence of chemotherapy treatment in the previous 2 weeks. - absence of treatment with brentuximab in the last 2 months. - absence of treatment with anti-PD1 in the previous 6 weeks. - absence of treatment with corticosteroids (any dose), with the exception of hydrocortisone (maximum 10 mg/m2). - absence of treatment with G-CSF/GM-CSF. - absence of treatment with any immunosuppressant (calcineurin inhibition, mycophenolate, rapamycin, anti-IL-6 or IL-6R antibodies, methotrexate) in the previous 2 weeks. Before starting lymphodepleting chemotherapy, the following requirements (all) must be met: - absence of clinically relevant active bacterial, fungal or viral infection. Viral infections that must be evaluated before starting chemotherapy are: influenza virus, respiratory syncytial virus and SarsCov2, using a nasopharyngeal aspirate whose result is negative. - absence of antineoplastic treatment in the previous 2 weeks. - absence of treatment with corticosteroids (any dose), with the exception of hydrocortisone (maximum 10 mg/m2). - absence of treatment with G-CSF/GM-CSF. - absence of treatment with any immunosuppressant (calcineurin inhibition, mycophenolate, rapamycin, anti-IL-6 antibodies, methotrexate) in the previous 2 weeks. Previous allogeneic hemopoietic transplant within 12 weeks prior to screening. Presence of acute graft-versus-receptor disease (GVHD) or chronic GVHD requiring immunosuppressive treatment of any type Active HBV or HCV infection HIV infection Active, clinically relevant bacterial, fungal or viral infection. Active infiltration of the CNS by lymphoma. Previous infiltration by lymphoma is not exclusive if there is demonstration of absence of disease in the CNS prior to treatment. Abnormal kidney and liver functions, with creatinine and/or bilirubin levels 2 and 3 times higher than the normal limit value, respectively, except when the alterations are attributable to lymphoma (only in the case of liver alliteration). Patients with decreased ventricular ejection fraction (FEV) (less than 40%),

symptomatic heart failure, or both

Calendario

(Última actualización: 10/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
03/03/2020	05/10/2020	09/10/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
14/10/2025	No aportado	No aportado	No aportado	No aportado

Promotor

Fundacio Institut De Recerca De L'Hospital De La Santa Creu I Sant Pau Spain

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Monetary support: N/A

Tipo de promotor: No comercial

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Centros

Activo (05/10/2020)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Medicamentos

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: L04AC07 - TOCILIZUMAB

Principios Activos: N/A

Experimental

Fludarabina Accord 25 mg/ml concentrado para solución inyectable y para perfusión.

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS INFUSION

Código ATC: L01BB05 - FLUDARABINA

Principios Activos: N/A

Experimental

Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

Código ATC: L01AA09 - BENDAMUSTINA

Principios Activos: N/A

Experimental

Genoxal 200 mg polvo para solución inyectable y para perfusión

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS INFUSION

Código ATC: L01AA01 - CICLOFOSFAMIDA

Principios Activos: N/A

Experimental

HSP-CAR30

INJECTABLE

INTRAVENOUS

-

Principios Activos: N/A

Experimental

Sin resultados

Inmmunotherapy with peripheral blood, autologous, a dult T cells, expanded and transduced (gene modified) with a lentiviral vector expressing an anti-CD30-chimeric antigen receptor with 4-1-BB and CD3z costimulatory sequences in patients with Classical Hodgkin lymphoma and non-Hodgkin CD30+ T cell lymphoma.

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	40
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	safety, effectiveness	NO

Information

Identifier
2024-515624-36-00 (CTIS)

Protocol Code
No aportado

Transitioned 2019-001263-70

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

Investigated Disease
Refractary or relapse non-Hodgkin T CD30+ lymphoma.
Refractary or relapse Hodgkin T CD30+ lymphoma

Scientific Title

Inmmunotherapy with peripheral blood, autologous, a dult T cells, expanded and transduced (gene modified) with a lentiviral vector expressing an anti-CD30-chimeric antigen receptor with 4-1-BB and CD3z costimulatory sequences in patients with Classical Hodgkin lymphoma and non-Hodgkin CD30+ T cell lymphoma.

Rationale

Not provided

Main Objective

To evaluate the safety and toxicity of HSP-CAR30 cell administration.

Primary Endpoints

Dose-limiting toxicity (DLT): the proportion of patients with DLT in the first month after infusion of HSP-CAR30 cells will be calculated, for each dose, together with the 95% confidence interval.
Safety: Data on the type and frequency of AEs will be collected for each dose level, starting from the infusion of HSP-CAR30 cells and up to 30 days thereafter.
Answer: the percentage of responses (RC, RP and RG) will be analyzed according to RECIL 2017 criteria and its 95% confidence interval will be calculated. Only patients who receive the infusion of HSP-CAR30 cells will be evaluable for response. In no case will patients who do not present detectable disease by PET-CT (patient in CR), determined in the 30 days prior to the infusion of HSPCAR30 cells, be considered for response analysis.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

All patients must sign informed consent before the start of any procedure. General status according to ECOG scale: 0-1. FEV1 > 39%; DLCO and FVC > 39% of normal theoretical values. Absence of significant ventricular dysfunction: left ventricular ejection fraction >40%. Total bilirubin and transaminases < 3 times the maximum normal value, unless attributable to lymphoma. Creatinine < 2 times the maximum normal value and clearance > 40 mL/min. Negative serology for HIV, HBV and HCV. In the case of patients with positive serology for HBV or HCV, they must have a viral load of 0 measured by quantitative PCR Absence of active, clinically relevant bacterial or viral infection. A diagnostic test for influenza virus, respiratory syncytial (nasopharyngeal aspirate) and SarsCov2 must be performed in ALL patients, prior to starting treatment, with a negative result. All patients must have measurable disease (detected by PET-CT) at the time of inclusion. Patients with classic Hodgkin's disease: 1. Age 18-80 years or older Patients with classic Hodgkin's disease: 2. Patients in relapse after an autologous transplant of hemopoietic progenitors and who have previously received brentuximab vedotin and anti-PDL1 antibodies in any of the rescue treatments, without achieving CR. Patients with classic Hodgkin's disease: 3. Primary refractory patients (after 1st line of treatment) and who do not achieve CR after rescue treatments that include brentuximab and anti-PDL1 antibodies. Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 1. CD30 expression (determined by immunohistochemistry) in > 90% of tumor cells for peripheral T lymphoma Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 2. Age 18 years or older Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 3. Patients in relapse after an autologous transplant of hemopoietic progenitors. Patients with anaplastic large cell T lymphoma (ALK + and ALK -) and peripheral T lymphoma (NOS and angioimmunoblastic): 4. Primary refractory patients (after 1st line of treatment that includes anthracycline) who do not achieve CR after rescue chemotherapy (type ESHAP, ICE, DHAP, Gemox or brentuximab vedotin).

Exclusion criteria

General condition determined according to ECOG scale: 2-4. Presence of cirrhosis or active hepatitis due to HBV or HCV virus Patients with concomitant severe neurological or psychiatric illness Presence of active autoimmune or rheumatologic disease requiring systemic treatment with any immunosuppressant (including prednisone at any dose). Pneumopathy of any type that causes a DLC <39% Major surgery in the 6 weeks prior to the start of inclusion. Any concomitant antineoplastic treatment. Pregnant or lactating patients. Previous or concurrent neoplasms. Except: basal cell or squamous cell carcinoma, history of carcinoma in situ with previous curative treatment, solid neoplasia with complete resection and in remission for >3 years. Before starting lymphoapheresis, all of the following requirements must be met: - absolute lymphocyte count in peripheral blood > 100/ml. - absence of chemotherapy treatment in the previous 2 weeks. - absence of treatment with brentuximab in the last 2 months. - absence of treatment with anti-PD1 in the previous 6 weeks. - absence of treatment with corticosteroids (any dose), with the exception of hydrocortisone (maximum 10 mg/m2). - absence of treatment with G-CSF/GM-CSF. - absence of treatment with any immunosuppressant (calcineurin inhibition, mycophenolate, rapamycin, anti-IL-6 or IL-6R antibodies, methotrexate) in the previous 2 weeks. Before starting lymphodepleting chemotherapy, the following requirements (all) must be met: - absence of clinically relevant active bacterial, fungal or viral infection. Viral infections that must be evaluated before starting chemotherapy are: influenza virus, respiratory syncytial virus and SarsCov2, using a nasopharyngeal aspirate whose result is negative. - absence of antineoplastic treatment in the previous 2 weeks. - absence of treatment with corticosteroids (any dose), with the exception of hydrocortisone (maximum 10 mg/m2). - absence of treatment with G-CSF/GM-CSF. - absence of treatment with any immunosuppressant (calcineurin inhibition, mycophenolate, rapamycin, anti-IL-6 antibodies, methotrexate) in the previous 2 weeks. Previous allogeneic hemopoietic transplant within 12 weeks prior to screening. Presence of acute graft-versus-receptor disease (GVHD) or chronic GVHD requiring immunosuppressive treatment of any type Active HBV or HCV infection HIV infection Active, clinically relevant bacterial, fungal or viral infection. Active infiltration of the CNS by lymphoma. Previous infiltration by lymphoma is not exclusive if there is demonstration of absence of disease in the CNS prior to treatment. Abnormal kidney and liver functions, with creatinine and/or bilirubin levels 2 and 3 times higher than the normal limit value, respectively, except when the alterations are attributable to lymphoma (only in the case of liver alliteration). Patients with decreased ventricular ejection fraction (FEV) (less than 40%),

symptomatic heart failure, or both

Calendar

(Last Update: 10/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
03/03/2020	05/10/2020	09/10/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
14/10/2025	Not aported	Not aported	Not aported	Not aported

Sponsor

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Monetary support: N/A

Sponsor type: No commercial

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Sites

Active (05/10/2020)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Medication

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: L04AC07 - TOCILIZUMAB

Active Principles: N/A

Experimental

Fludarabina Accord 25 mg/ml concentrado para solución inyectable y para perfusión.

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS INFUSION

ATC code: L01BB05 - FLUDARABINA

Active Principles: N/A

Experimental

Levact 2,5 mg/ml poudre pour solution à diluer pour perfusion

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

ATC code: L01AA09 - BENDAMUSTINA

Active Principles: N/A

Experimental

Genoxal 200 mg polvo para solución inyectable y para perfusión

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS INFUSION

ATC code: L01AA01 - CICLOFOSFAMIDA

Active Principles: N/A

Experimental

HSP-CAR30

INJECTABLE

INTRAVENOUS

-

Active Principles: N/A

Experimental

No results