IMMUNOTHERAPY WITH DIFFERENTIATED T CELLS, ADULTS, AUTOLOGOUS, FROM PERIPHERAL BLOOD, SELECTED BY CD62L EXPRESSION, EXPANDED AND TRANSDUCED (GENETICALLY MODIFIED) THROUGH A LENTIVIRAL VECTOR TO EXPRESS A CHIMERIC RECEPTOR WITH ANTI-CD19 SPECIFICITY ASSOCIATED WITH CO-STIMULATORY SEQUENCES 4-1-BB AND CD3 IN PATIENTS WITH B-CELL NON-HODGKIN LYMPHOMA.

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	40
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	Terapia celular

Información

Identificador

2024-519790-19-00 (CTIS)

Cod. Protocolo

No aportado

Transicionado 2020-003133-38

Área terapéutica

·Equipos y técnicas terapéuticas, analíticas y diagnósticas [E] - Técnicas terapéuticas [E02]
·Enfermedades [C] - Hematología [C15]

Enfermedad investigada

Relapsed/refractory large B-cell non-Hodgkin lymphoma, mantle cell lymphoma, and follicular lymphoma

Título Científico

IMMUNOTHERAPY WITH DIFFERENTIATED T CELLS, ADULTS, AUTOLOGOUS, FROM PERIPHERAL BLOOD, SELECTED BY CD62L EXPRESSION, EXPANDED AND TRANSDUCED (GENETICALLY MODIFIED) THROUGH A LENTIVIRAL VECTOR TO EXPRESS A CHIMERIC RECEPTOR WITH ANTI-CD19 SPECIFICITY ASSOCIATED WITH CO-STIMULATORY SEQUENCES 4-1-BB AND CD3 IN PATIENTS WITH B-CELL NON-HODGKIN LYMPHOMA.

Justificación

No aportado

Objetivo Principal

Evaluate the safety, toxicity, and efficacy of the administration of autologous memory T cells, mature, expanded ex vivo and genetically modified with a chimeric antigen receptor (CAR) targeting the CD19 antigen

Variables de Evaluación Primaria

Safety associated with the infusion of HSP-CAR19M cells. In the expansion phase: evaluation of the safety and efficacy of HSP-CAR19M cell administration.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Analyze the persistence of CAR19 T cells
Analyze the response rate at 3 months post-procedure.
Analyze the impact of the procedure on progression-free survival at 2 years.
Analyze overall survival (OS) at 2 years.
Analizar el implante y persistencia de las células T-CAR19.

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age > 18 years All patients must have measurable disease (detected by PET-CT or CT) at the time of inclusion. Patients with Diffuse Large B-Cell Lymphoma (DLBCL): Histological diagnosis (WHO) of LDCGB or grade 3B follicular lymphoma, and Relapsed or refractory to 2 lines of treatment (including doxorubicin and anti-CD20 monoclonal antibody) or relapse after autologous hematopoietic stem cell transplantation from peripheral blood. Patients with Mantle Cell Lymphoma (MCL): Histological diagnosis (WHO) of MCL, including classical and blastoid variants, and Relapsed or refractory after two lines of treatment, which must include an anti-CD20 monoclonal antibody and a BTK inhibitor, or relapse after an autologous hematopoietic stem cell transplantation in patients who previously received a BTK inhibitor. Patients with Follicular Lymphoma (FL): Histological diagnosis (WHO) of FL grade 1-3a, and Relapsed or refractory to two lines of treatment (including anti-CD20 monoclonal antibody) or meet the criteria for early relapse (POD24) within the first 24 months after the start of initial treatment: relapse/refractoriness after one treatment (including anti-CD20 monoclonal antibody) or relapse after autologous hematopoietic stem cell transplantation. General condition according to ECOG scale: 0-2. FEV1 > 40%; DLCO and FVC > 40% of the predicted normal values. Absence of significant ventricular dysfunction: left ventricular ejection fraction > 40%. Total bilirubin and transaminases < 4 times the upper normal limit, unless attributable to lymphoma. Creatinine < 2 times the upper normal limit and clearance > 40 mL/min. Negative serology for HIV, HBV, and HCV. For patients with positive serology for HBV or HCV, a viral load of 0 must be confirmed via quantitative PCR. Absence of uncontrolled active bacterial, viral, or fungal infection. All patients must sign an informed consent form prior to the initiation of any procedure.

Criterios de Exclusión

General condition determined by ECOG scale: 3-4. Presence of active autoimmune or rheumatologic disease requiring systemic treatment with any immunosuppressor. Lung disease of any type that results in a DLCO < 40%. Major surgery within 6 weeks prior to inclusion. Any concomitant anticancer treatment. Pregnant or breastfeeding patients. Active infection with HBV or HCV. HIV infection. Uncontrolled active bacterial, fungal, or viral infection. Active CNS infiltration by lymphoma. Previous lymphoma infiltration is not exclusionary if there is evidence of absence of disease in the CNS prior to treatment. Abnormal renal and hepatic function, with creatinine and/or bilirubin levels more than 2 and 4 times higher than the normal limit, respectively, except when the abnormalities are attributable to lymphoma (only in cases of hepatic alteration). Patients with a left ventricular ejection fraction (LVEF) less than 40%, symptomatic heart failure, or both. Presence of cirrhosis. Patients with concomitant severe neurological or psychiatric disease.

Calendario

(Última actualización: 29/09/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/07/2022	25/01/2023	31/01/2023	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

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

Calle Sant Quinti 77-79

Contact Person

Alejandra Espinosa

935537796

UICEC@santpau.cat

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

CEIm Fundacio de Gestio Sanitaria Hospital de la Santa Creu i Sant Pau

C/ Sant Quintí, 77-79. Planta 1a. Despacho 95 08041 Barcelona

ceimsantpau@santpau.cat

935537813

Centros

No iniciado (14/07/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

No iniciado (14/07/2022)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

Medicamentos

Beneflur10 mg comprimidos recubiertos con película

FILM-COATED TABLET

INTRAVENOUS INFUSION

Código ATC: L01BB05 - FLUDARABINA

Principios Activos: N/A

Experimental

Genoxal 200 mg polvo para solución inyectable y para perfusión

SOLUTION FOR INJECTION/INFUSION

INTRAVENIOUS INFUSION

Código ATC: L01AA01 - CICLOFOSFAMIDA

Principios Activos: N/A

Experimental

HSP-CAR19M

INFUSION

INTRAVENOUS INFUSION

Código ATC: L01XL - TERAPIA GENICA Y CELULAR ANTINEOPLASICA

Principios Activos: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

Código ATC: L04AC07 - TOCILIZUMAB

Principios Activos: N/A

Experimental

Levact 2,5 mg/ml, polvo para concentrado para solución para perfusión.

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: L01AA09 - BENDAMUSTINA

Principios Activos: N/A

Experimental

Sin resultados

IMMUNOTHERAPY WITH DIFFERENTIATED T CELLS, ADULTS, AUTOLOGOUS, FROM PERIPHERAL BLOOD, SELECTED BY CD62L EXPRESSION, EXPANDED AND TRANSDUCED (GENETICALLY MODIFIED) THROUGH A LENTIVIRAL VECTOR TO EXPRESS A CHIMERIC RECEPTOR WITH ANTI-CD19 SPECIFICITY ASSOCIATED WITH CO-STIMULATORY SEQUENCES 4-1-BB AND CD3 IN PATIENTS WITH B-CELL NON-HODGKIN LYMPHOMA.

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	40
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	Cellular therapy

Information

Identifier
2024-519790-19-00 (CTIS)

Protocol Code
No aportado

Transitioned 2020-003133-38

Therapeutic area
·Analytical, Diagnostic and Therapeutic Techniques and Equipment [E] - Therapeutic techniques [E02]
·Diseases [C] - Hemic and Lymphatic Diseases [C15]

Investigated Disease
Relapsed/refractory large B-cell non-Hodgkin lymphoma, mantle cell lymphoma, and follicular lymphoma

Scientific Title

IMMUNOTHERAPY WITH DIFFERENTIATED T CELLS, ADULTS, AUTOLOGOUS, FROM PERIPHERAL BLOOD, SELECTED BY CD62L EXPRESSION, EXPANDED AND TRANSDUCED (GENETICALLY MODIFIED) THROUGH A LENTIVIRAL VECTOR TO EXPRESS A CHIMERIC RECEPTOR WITH ANTI-CD19 SPECIFICITY ASSOCIATED WITH CO-STIMULATORY SEQUENCES 4-1-BB AND CD3 IN PATIENTS WITH B-CELL NON-HODGKIN LYMPHOMA.

Rationale

Not provided

Main Objective

Evaluate the safety, toxicity, and efficacy of the administration of autologous memory T cells, mature, expanded ex vivo and genetically modified with a chimeric antigen receptor (CAR) targeting the CD19 antigen

Primary Endpoints

Safety associated with the infusion of HSP-CAR19M cells. In the expansion phase: evaluation of the safety and efficacy of HSP-CAR19M cell administration.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Analyze the persistence of CAR19 T cells
Analyze the response rate at 3 months post-procedure.
Analyze the impact of the procedure on progression-free survival at 2 years.
Analyze overall survival (OS) at 2 years.
Analizar el implante y persistencia de las células T-CAR19.

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age > 18 years All patients must have measurable disease (detected by PET-CT or CT) at the time of inclusion. Patients with Diffuse Large B-Cell Lymphoma (DLBCL): Histological diagnosis (WHO) of LDCGB or grade 3B follicular lymphoma, and Relapsed or refractory to 2 lines of treatment (including doxorubicin and anti-CD20 monoclonal antibody) or relapse after autologous hematopoietic stem cell transplantation from peripheral blood. Patients with Mantle Cell Lymphoma (MCL): Histological diagnosis (WHO) of MCL, including classical and blastoid variants, and Relapsed or refractory after two lines of treatment, which must include an anti-CD20 monoclonal antibody and a BTK inhibitor, or relapse after an autologous hematopoietic stem cell transplantation in patients who previously received a BTK inhibitor. Patients with Follicular Lymphoma (FL): Histological diagnosis (WHO) of FL grade 1-3a, and Relapsed or refractory to two lines of treatment (including anti-CD20 monoclonal antibody) or meet the criteria for early relapse (POD24) within the first 24 months after the start of initial treatment: relapse/refractoriness after one treatment (including anti-CD20 monoclonal antibody) or relapse after autologous hematopoietic stem cell transplantation. General condition according to ECOG scale: 0-2. FEV1 > 40%; DLCO and FVC > 40% of the predicted normal values. Absence of significant ventricular dysfunction: left ventricular ejection fraction > 40%. Total bilirubin and transaminases < 4 times the upper normal limit, unless attributable to lymphoma. Creatinine < 2 times the upper normal limit and clearance > 40 mL/min. Negative serology for HIV, HBV, and HCV. For patients with positive serology for HBV or HCV, a viral load of 0 must be confirmed via quantitative PCR. Absence of uncontrolled active bacterial, viral, or fungal infection. All patients must sign an informed consent form prior to the initiation of any procedure.

Exclusion criteria

General condition determined by ECOG scale: 3-4. Presence of active autoimmune or rheumatologic disease requiring systemic treatment with any immunosuppressor. Lung disease of any type that results in a DLCO < 40%. Major surgery within 6 weeks prior to inclusion. Any concomitant anticancer treatment. Pregnant or breastfeeding patients. Active infection with HBV or HCV. HIV infection. Uncontrolled active bacterial, fungal, or viral infection. Active CNS infiltration by lymphoma. Previous lymphoma infiltration is not exclusionary if there is evidence of absence of disease in the CNS prior to treatment. Abnormal renal and hepatic function, with creatinine and/or bilirubin levels more than 2 and 4 times higher than the normal limit, respectively, except when the abnormalities are attributable to lymphoma (only in cases of hepatic alteration). Patients with a left ventricular ejection fraction (LVEF) less than 40%, symptomatic heart failure, or both. Presence of cirrhosis. Patients with concomitant severe neurological or psychiatric disease.

Calendar

(Last Update: 29/09/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/07/2022	25/01/2023	31/01/2023	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

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

Calle Sant Quinti 77-79

Contact Person

Alejandra Espinosa

935537796

UICEC@santpau.cat

Monetary support: N/A

Sponsor type: No commercial

Ceim

CEIm Fundacio de Gestio Sanitaria Hospital de la Santa Creu i Sant Pau

C/ Sant Quintí, 77-79. Planta 1a. Despacho 95 08041 Barcelona

ceimsantpau@santpau.cat

935537813

Sites

not initialized (14/07/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

not initialized (14/07/2022)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

Medication

Beneflur10 mg comprimidos recubiertos con película

FILM-COATED TABLET

INTRAVENOUS INFUSION

ATC code: L01BB05 - FLUDARABINA

Active Principles: N/A

Experimental

Genoxal 200 mg polvo para solución inyectable y para perfusión

SOLUTION FOR INJECTION/INFUSION

INTRAVENIOUS INFUSION

ATC code: L01AA01 - CICLOFOSFAMIDA

Active Principles: N/A

Experimental

HSP-CAR19M

INFUSION

INTRAVENOUS INFUSION

ATC code: L01XL - TERAPIA GENICA Y CELULAR ANTINEOPLASICA

Active Principles: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

ATC code: L04AC07 - TOCILIZUMAB

Active Principles: N/A

Experimental

Levact 2,5 mg/ml, polvo para concentrado para solución para perfusión.

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: L01AA09 - BENDAMUSTINA

Active Principles: N/A

Experimental

No results