CLINICAL TRIAL FOR THE PREVENTION OF CYTOMEGALOVIRUS INFECTION IN HEMATOPOIETIC STEM CELL TRANSPLANTATION IN PATIENTS WITH NO AVAILABLE 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	32
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	profilaxis	Terapia celular

Información

Identificador

2024-520020-28-00 (CTIS)

Cod. Protocolo

INMUNOCELL-CTMV

Transicionado 2019-002311-26

Área terapéutica

Enfermedades [C] - Enfermedades víricas [C02]|

Enfermedad investigada

Cytomegalovirus infection post allogeneic allogeneic HLA-identical familial PHT

Título Científico

PILOT ANTI-CMV CLINICAL TRIAL: PROPHYLAXIS OF CYTOMEGALOVIRUS INFECTION IN HLA-IDENTICAL FAMILIAL ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION WITH ADVANCED CELLULAR

IMMUNOTHERAPY IN PATIENTS WITHOUT SPECIFIC PHARMACOLOGYCAL PROPHYLAXIS AVAILABLE

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of antiviral prophylaxis with specific CTLs against CMV in reducing the incidence of CMV infection at 100 days posttransplant, according to historical controls of the haematology
service of the Hospital Universitario Marqués de Valdecilla

Variables de Evaluación Primaria

efficacy is the incidence of CMV infection AT DAY 100 POST-TPH (measured as viral load >200 copies in 2 determinations or >1000 in 1 determination [PCRq]).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Efficiency: Assess the need for CMV treatment Efficiency:Evaluate the incidence of CMV disease, its characteristics and mortality Safety: Evaluate the occurrence of immediate (<24h) or delayed infusional reactions. Safety: To evaluate the incidence and severity of adverse events (AEs) and serious adverse events (SAEs), in terms of secondary attachment failure, XML File Identifier: UpbqLT1nsMdVMooHTktbNMVzXmA= Page 10/22 acute and chronic graft-versus-recipient disease (GVHD) and overall mortality. Exploratory:To evaluate the persistence of allogeneic CMV-specific memory T lymphocytes by flow cytometry on the day of cell infusion (+-7 days) at 1 month and 2 months after hematopoietic progenitor infusion Exploratory:To evaluate post-HAPLO immune reconstitution at day 30, 60, 90 and 180 post-TPH

Variables de Evaluación Secundaria

Assess the need for CMV treatment
To evaluate the incidence of CMV disease
to assess the presence of allogeneic CMV-specific memory T lymphocytes

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Adult patients (over 18 years of age), whether or not diagnosed with hematologic malignancy, who have received an allogeneic HSCT hematopoietic progenitor transplant from HLA-identical family donors b. The donor will be screened to determine suitability according to the HSCT hematopoietic progenitor donor evaluation criteria C. The donor has to also sign a written informed consent prior to inclusion Non-candidates to receive Letermovir Source of HSC progenitors: peripheral blood or bone marrow Patients whose donor is CMV seropositive Negative pregnancy test in women Written informed consent signed by the patient or legal representative Partial recovery of the hematopoietic implant (absolute neutrophil count >0.5 x10^9 cells/L for at least 3 consecutive post-HSCT determinations) Specific inclusion criteria for donors: a. Donors will be selected if they meet HLA identity criteria and are CMV seropositive

Criterios de Exclusión

MUST NOT MEET ANY OF THE ESTABLISHED CRITERIA for the prescription of LETERMOVIR in CMV seropositive adult recipients of an allogeneic HSCT: ECOG > or = 3 Organ toxicity greater than grade 3 according to CTCAE Version 5.0 Uncontrolled infection, defined by fever and/or hemodynamic instability and/or unresolved infectious focus. Persistent fever (>38ºC) in the 3 days prior to the infusion Relapse or active and uncontrolled progression of the malignant disease CMV viral reactivation prior to the day of infusion (21 post-HSCT) requiring anti-viral treatment (more than 200 copies of CMV by PCR in 2 determinations or more than 1000 in 1 determination). Previous therapy with Letermovir Specific exclusion criteria for donors: a. Active infection at the time of lymphoapheresis Related donor with at least one mismatch at one of the HLA locus (HLA-A, -B or -DR) Haploidentical donor Unrelated donor with at least one mismatch at one of the four HLA gene loci (HLA-A, -B, -C and -DRB1) Use of cord blood Use of graft with ex vivo T-lymphocyte depletion GvHD grade 2 or higher requiring the use of systemic corticosteroids (doses 1mg/kg/day of prednisone or equivalent doses of other corticosteroids AND MUST NOT MEET ANY OF THE CRITERIA BELOW to participate in the study: Treatment at the time of cell infusion with corticosteroid doses greater than 0.5mg/kg/day of prednisone or equivalents

Calendario

(Última actualización: 23/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/12/2021	26/03/2022	No aportado	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

Instituto De Investigacion Marques De Valdecilla Spain

Avenida Del Cardenal Herrera Oria S/n

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de Cantabria

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Centros

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

hematologia

Activo (26/03/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Hematología

Medicamentos

-

-

INJECTION

Código ATC: J05AX - OTROS ANTIVIRALES

Principios Activos: N/A

Experimental

Sin resultados

CLINICAL TRIAL FOR THE PREVENTION OF CYTOMEGALOVIRUS INFECTION IN HEMATOPOIETIC STEM CELL TRANSPLANTATION IN PATIENTS WITH NO AVAILABLE 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	32
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	prophylaxis	Cellular therapy

Information

Identifier
2024-520020-28-00 (CTIS)

Protocol Code
INMUNOCELL-CTMV

Transitioned 2019-002311-26

Therapeutic area
Diseases [C] - Virus Diseases [C02]|

Investigated Disease
Cytomegalovirus infection post allogeneic allogeneic HLA-identical familial PHT

Scientific Title
PILOT ANTI-CMV CLINICAL TRIAL: PROPHYLAXIS OF CYTOMEGALOVIRUS INFECTION IN HLA-IDENTICAL FAMILIAL ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION WITH ADVANCED CELLULAR

IMMUNOTHERAPY IN PATIENTS WITHOUT SPECIFIC PHARMACOLOGYCAL PROPHYLAXIS AVAILABLE

Rationale

Not provided

Main Objective

To evaluate the efficacy of antiviral prophylaxis with specific CTLs against CMV in reducing the incidence of CMV infection at 100 days posttransplant, according to historical controls of the haematology
service of the Hospital Universitario Marqués de Valdecilla

Primary Endpoints

efficacy is the incidence of CMV infection AT DAY 100 POST-TPH (measured as viral load >200 copies in 2 determinations or >1000 in 1 determination [PCRq]).

Temporary moments of secondary assessment

Not provided

Secondary Objective

Efficiency: Assess the need for CMV treatment Efficiency:Evaluate the incidence of CMV disease, its characteristics and mortality Safety: Evaluate the occurrence of immediate (<24h) or delayed infusional reactions. Safety: To evaluate the incidence and severity of adverse events (AEs) and serious adverse events (SAEs), in terms of secondary attachment failure, XML File Identifier: UpbqLT1nsMdVMooHTktbNMVzXmA= Page 10/22 acute and chronic graft-versus-recipient disease (GVHD) and overall mortality. Exploratory:To evaluate the persistence of allogeneic CMV-specific memory T lymphocytes by flow cytometry on the day of cell infusion (+-7 days) at 1 month and 2 months after hematopoietic progenitor infusion Exploratory:To evaluate post-HAPLO immune reconstitution at day 30, 60, 90 and 180 post-TPH

Secondary Endpoints

Assess the need for CMV treatment
To evaluate the incidence of CMV disease
to assess the presence of allogeneic CMV-specific memory T lymphocytes

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult patients (over 18 years of age), whether or not diagnosed with hematologic malignancy, who have received an allogeneic HSCT hematopoietic progenitor transplant from HLA-identical family donors b. The donor will be screened to determine suitability according to the HSCT hematopoietic progenitor donor evaluation criteria C. The donor has to also sign a written informed consent prior to inclusion Non-candidates to receive Letermovir Source of HSC progenitors: peripheral blood or bone marrow Patients whose donor is CMV seropositive Negative pregnancy test in women Written informed consent signed by the patient or legal representative Partial recovery of the hematopoietic implant (absolute neutrophil count >0.5 x10^9 cells/L for at least 3 consecutive post-HSCT determinations) Specific inclusion criteria for donors: a. Donors will be selected if they meet HLA identity criteria and are CMV seropositive

Exclusion criteria

MUST NOT MEET ANY OF THE ESTABLISHED CRITERIA for the prescription of LETERMOVIR in CMV seropositive adult recipients of an allogeneic HSCT: ECOG > or = 3 Organ toxicity greater than grade 3 according to CTCAE Version 5.0 Uncontrolled infection, defined by fever and/or hemodynamic instability and/or unresolved infectious focus. Persistent fever (>38ºC) in the 3 days prior to the infusion Relapse or active and uncontrolled progression of the malignant disease CMV viral reactivation prior to the day of infusion (21 post-HSCT) requiring anti-viral treatment (more than 200 copies of CMV by PCR in 2 determinations or more than 1000 in 1 determination). Previous therapy with Letermovir Specific exclusion criteria for donors: a. Active infection at the time of lymphoapheresis Related donor with at least one mismatch at one of the HLA locus (HLA-A, -B or -DR) Haploidentical donor Unrelated donor with at least one mismatch at one of the four HLA gene loci (HLA-A, -B, -C and -DRB1) Use of cord blood Use of graft with ex vivo T-lymphocyte depletion GvHD grade 2 or higher requiring the use of systemic corticosteroids (doses 1mg/kg/day of prednisone or equivalent doses of other corticosteroids AND MUST NOT MEET ANY OF THE CRITERIA BELOW to participate in the study: Treatment at the time of cell infusion with corticosteroid doses greater than 0.5mg/kg/day of prednisone or equivalents

Calendar

(Last Update: 23/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/12/2021	26/03/2022	Not aported	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

Instituto De Investigacion Marques De Valdecilla Spain

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

hematologia

Active (26/03/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Hematología

Medication

-

-

INJECTION

ATC code: J05AX - OTROS ANTIVIRALES

Active Principles: N/A

Experimental

No results