CAR T-cell therapy long term follow-up

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento , Mujeres embarazas	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) , Recién nacidos (0-27 días)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	952
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	Terapia génica

Información

Identificador
2023-508128-37-00 (CTIS)

Cod. Protocolo
CCTL019A2205B

Transicionado 2014-001673-14

Área terapéutica
·Enfermedades [C] - Hematología [C15]
·Enfermedades [C] - Patologías del sistema inmunitario [C20]

Enfermedad investigada
All patients who have been treated with Novartis or Penn CAR T-cell therapy for any indication

Título Científico
Long Term Follow-Up of Patients Exposed to Lentiviral-Based CAR T-CellTherapy

Justificación

No aportado

Objetivo Principal

Describe selected, delayed AEs that are suspected to be related to previous CAR T-cell therapy as outlined in current Health Authority guidelines

Variables de Evaluación Primaria

Proportion of patients with events in each of the following categories: For participants treated for non-hematology/non-oncology indications: New primary malignanciesFor participants with hematology/oncology indications: New secondary malignanciesNew serious infectionsNew incidence of serious neurologic disorderNew incidence or exacerbation of a prior rheumatologic or other autoimmune disorderNew incidence of a hematologic disorderOther adverse events considered related to CAR T-cell thera

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Monitor the persistence of modified T-cells in peripheral blood Monitor for RCL (Replication Competent Lentivirus) Assess the long-term efficacy of CAR T-cell therapy for hematology/oncology patients Monitor lymphocyte levels Describe the growth, development, and female reproductive status for patients who were aged < 18 years at the time of the initial CAR T cell therapy

Variables de Evaluación Secundaria

Proportion of patients with detectable CAR transgene levels in peripheral blood by qPCR at pre-specified time points
Proportion of patients with detectable RCL by VSV-G qPCR in peripheral blood at pre-specified time points
Proportion of patients who relapse or progress among patients who had not relapsed or progressed at study entry/re-entry Incidence of death Note: For non-hematology/non-oncology patients, though there will be no formal assessments for efficacy, data on disease indication management will be captured in the Concomitant Medication CRF (e.g., rescue medication including immunosuppressive medications).
B and T lymphocyte counts
Height and weight, Tanner staging, menstruation status The pregnancy status for female patients will be captured in the CRF. For female partners of male patients if female partners provide consent, pregnancy outcome and data on live births for infants at birth, 3 months and 1 year of age is captured in Novartis safety forms.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients must have received CAR T-cell therapy within one of the following: Novartis or Penn sponsored CAR T-cell treatment trials where CAR T-cell therapy was given as monotherapy or as combination therapy. Novartis managed access programs (MAPs) outside of the commercial setting, i.e. where CAR T-cell therapy was intended to be given in the setting of a Novartis or Penn sponsored CAR T-cell treatment trial
Patients must provide informed consent/assent prior to their entry into this study

Criterios de Exclusión

There are no specific exclusion criteria for this study.

Calendario

(Última actualización: 13/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
01/12/2015	15/01/2016	16/07/2018	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

Novartis Pharma Services AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Fundacio Sant Joan de Deu

Santa Rosa, 39-57, 3a planta 08950 Esplugues de Llobregat

frecerca.ceic@sjd.es

Centros

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (23/09/2019)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Servicio de Hematología y Hemoterapia

Activo (25/09/2019)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Activo (18/03/2021)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Activo (18/02/2022)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Activo (16/02/2021)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Hematología

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Oncology

Activo (13/06/2016)

HOSPITAL DE SANT JOAN DE DÉU

ESPLUGUES DE LLOBREGAT

BARCELONA

Hematologia

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Oncology

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Department of Rheumatology

Activo (19/08/2020)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

Hematología

Activo (25/02/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Oncología y Hematología Pediátricas

Activo (26/11/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Universitario La Paz

Madrid

MADRID

Hematology and Hemotherapy

Activo (22/03/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Activo (13/09/2019)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Institut Català D'oncologia - Hospital Duran I Reynals

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

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Oncology

Medicamentos

TISAGENLECLEUCEL
DISPERSION FOR INFUSION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Huérfano

Experimental

YTB323
DISPERSION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

PHE885
DISPERSION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

CAR T-cell therapy long term follow-up

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent , Pregnant women	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) , Newborn infants (0-27 days)
Gender	**Phases**	**Expected Participants**
Both	Phase III	952
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	Gene therapy

Information

Identifier
2023-508128-37-00 (CTIS)

Protocol Code
CCTL019A2205B

Transitioned 2014-001673-14

Therapeutic area
·Diseases [C] - Hemic and Lymphatic Diseases [C15]
·Diseases [C] - Immune System Diseases [C20]

Investigated Disease
All patients who have been treated with Novartis or Penn CAR T-cell therapy for any indication

Scientific Title
Long Term Follow-Up of Patients Exposed to Lentiviral-Based CAR T-CellTherapy

Rationale

Not provided

Main Objective

Describe selected, delayed AEs that are suspected to be related to previous CAR T-cell therapy as outlined in current Health Authority guidelines

Primary Endpoints

Proportion of patients with events in each of the following categories: For participants treated for non-hematology/non-oncology indications: New primary malignanciesFor participants with hematology/oncology indications: New secondary malignanciesNew serious infectionsNew incidence of serious neurologic disorderNew incidence or exacerbation of a prior rheumatologic or other autoimmune disorderNew incidence of a hematologic disorderOther adverse events considered related to CAR T-cell thera

Temporary moments of secondary assessment

Not provided

Secondary Objective

Monitor the persistence of modified T-cells in peripheral blood Monitor for RCL (Replication Competent Lentivirus) Assess the long-term efficacy of CAR T-cell therapy for hematology/oncology patients Monitor lymphocyte levels Describe the growth, development, and female reproductive status for patients who were aged < 18 years at the time of the initial CAR T cell therapy

Secondary Endpoints

Proportion of patients with detectable CAR transgene levels in peripheral blood by qPCR at pre-specified time points
Proportion of patients with detectable RCL by VSV-G qPCR in peripheral blood at pre-specified time points
Proportion of patients who relapse or progress among patients who had not relapsed or progressed at study entry/re-entry Incidence of death Note: For non-hematology/non-oncology patients, though there will be no formal assessments for efficacy, data on disease indication management will be captured in the Concomitant Medication CRF (e.g., rescue medication including immunosuppressive medications).
B and T lymphocyte counts
Height and weight, Tanner staging, menstruation status The pregnancy status for female patients will be captured in the CRF. For female partners of male patients if female partners provide consent, pregnancy outcome and data on live births for infants at birth, 3 months and 1 year of age is captured in Novartis safety forms.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients must have received CAR T-cell therapy within one of the following: Novartis or Penn sponsored CAR T-cell treatment trials where CAR T-cell therapy was given as monotherapy or as combination therapy. Novartis managed access programs (MAPs) outside of the commercial setting, i.e. where CAR T-cell therapy was intended to be given in the setting of a Novartis or Penn sponsored CAR T-cell treatment trial
Patients must provide informed consent/assent prior to their entry into this study

Exclusion criteria

There are no specific exclusion criteria for this study.

Calendar

(Last Update: 13/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
01/12/2015	15/01/2016	16/07/2018	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

Novartis Pharma Services AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Santa Rosa, 39-57, 3a planta 08950 Esplugues de Llobregat

frecerca.ceic@sjd.es

Sites

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (23/09/2019)

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SALAMANCA

Active (18/02/2022)

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VALENCIA

Active (16/02/2021)

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BARCELONA

Hematología

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

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Oncology

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

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Madrid

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Hematología

Active (25/02/2019)

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BARCELONA

Servicio de Oncología y Hematología Pediátricas

Active (26/11/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

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BARCELONA

Servicio de Hematología

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

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Madrid

MADRID

Hematology and Hemotherapy

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HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

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Active (13/09/2019)

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

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Oncology

Medication

TISAGENLECLEUCEL

DISPERSION FOR INFUSION

INTRAVENIOUS INFUSION

-

Active Principles: N/A

Orphan **Experimental**

YTB323

DISPERSION FOR INFUSION

INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

PHE885

DISPERSION FOR INFUSION

INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

No results