MK-4280A versus Physicians Choice Chemotherapy in PD-(L)1-refractory, relapsed/refractory Classical Hodgkin Lymphoma

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	149
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética, farmacogenómica, farmacoeconómica	NO

Información

Identificador
2023-503615-14-00 (CTIS)

Cod. Protocolo
MK-4280A-008

Transicionado 2022-000371-39

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

Enfermedad investigada
Relapsed or Refractory Classical Hodgkin Lymphoma

Título Científico
A Phase 2 Randomized Clinical Study of MK-4280A (coformulated favezelimab [MK-4280] plus pembrolizumab [MK-

3475]) Versus Physicians Choice Chemotherapy in PD-(L)1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma (KEYFORM-008)

Justificación

No aportado

Objetivo Principal

To compare MK-4280A to physicians choice chemotherapy with respect to PFS per Lugano response criteria by investigator assessment

Variables de Evaluación Primaria

Progression-Free Survival (PFS) per Lugano Response Criteria as Assessed by Investigator

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate MK-4280A to physicians choice chemotherapy with respect to OS
To evaluate MK-4280A and physicians choice chemotherapy with respect to ORR per Lugano response criteria by investigator assessment
To evaluate MK-4280A and physicians choice chemotherapy with respect to DOR per Lugano response criteria by investigator assessment
To evaluate the safety and tolerability of MK-4280A

Variables de Evaluación Secundaria

Overall Survival (OS)
Objective Response Rate (ORR) per Lugano Response Criteria as Assessed by Investigator
Duration of Response (DOR) per Lugano Response Criteria as Assessed by Investigator
Number of Participants Who Experienced At Least One Adverse Event (AE)
Number of Participants Who Discontinued Study Treatment Due to an Adverse Event (AE)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Has histologically confirmed diagnosis of classical Hodgkin lymphoma (cHL) that is 2-fluorodeoxyglucose-avid (FDG-avid).
Has relapsed (defined as disease progression after most recent therapy) or refractory (defined as failed to achieve CR or PR to most recent therapy) cHL and exhausted all available treatment options with known clinical benefit
Has progressed on treatment with an anti-PD-(L)1 monoclonal antibody (mAb) administered either as monotherapy or in combination with other checkpoint inhibitors or other therapies
Submits an archival (5 years) or newly obtained tumor tissue sample which has not been previously irradiated.

Criterios de Exclusión

Diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy.
Received prior radiotherapy within 2 weeks of start of study intervention or radiation related toxicities requiring corticosteroids.
Has not adequately recovered from major surgical procedure.
Known additional malignancy that is progressing or has required active treatment within the past 3 years.
History of human immunodeficiency virus (HIV).
Has had an allogeneic hematopoietic stem cell or solid organ transplantation within the last 5 years.
History of central nervous system (CNS) metastases or active CNS involvement.
Has an active autoimmune disease that has required systemic treatment in past 2 years except replacement therapy.
History of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease.
Has an active infection requiring systemic treatment.
History of hemophagocytic lymphohisticytosis.
Has an active seizure disorder that is not well controlled.
Has clinically significant (ie, active) cardiovascular disease.
Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization.

Calendario

(Última actualización: 25/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/09/2022	29/09/2022	18/10/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
11/12/2024	No aportado	No aportado	29/12/2025	08/01/2026

Promotor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Pallavi Madhusoodhan Pillai

+17325945583

pallavi.pillai@merck.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

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Centros

Cerrado (16/03/2026)

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Hematology Department

Cerrado (04/02/2025)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology Department

Cerrado (12/03/2026)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Hematología

Cerrado (20/02/2025)

HOSPITAL GENERAL UNIVERSITARIO DR. BALMIS

Alicante/Alacant

ALICANTE

Hematología

Cerrado (20/02/2025)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Haematology Department

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Haematology & Hemotherapy Department

Cerrado (09/03/2026)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Oncology

Cerrado (11/03/2025)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Hematología y Hemoterapia

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Haematology & Hemotherapy Department

Cerrado (18/02/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematology Department

Cerrado (03/03/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology Department

Medicamentos

-
-
INTRAVENOUS INFUSION

Código ATC: L01AA09 - BENDAMUSTINA
Principios Activos: N/A

Experimental

MK-4280A
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

-
-
INTRAVENOUS INFUSION

Código ATC: L01BC05 - GEMCITABINA
Principios Activos: N/A

Experimental

Sin resultados

MK-4280A versus Physicians Choice Chemotherapy in PD-(L)1-refractory, relapsed/refractory Classical Hodgkin Lymphoma

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	149
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacogenomics, pharmacoeconomic	NO

Information

Identifier
2023-503615-14-00 (CTIS)

Protocol Code
MK-4280A-008

Transitioned 2022-000371-39

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

Investigated Disease
Relapsed or Refractory Classical Hodgkin Lymphoma

Scientific Title
A Phase 2 Randomized Clinical Study of MK-4280A (coformulated favezelimab [MK-4280] plus pembrolizumab [MK-

3475]) Versus Physicians Choice Chemotherapy in PD-(L)1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma (KEYFORM-008)

Rationale

Not provided

Main Objective

To compare MK-4280A to physicians choice chemotherapy with respect to PFS per Lugano response criteria by investigator assessment

Primary Endpoints

Progression-Free Survival (PFS) per Lugano Response Criteria as Assessed by Investigator

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate MK-4280A to physicians choice chemotherapy with respect to OS
To evaluate MK-4280A and physicians choice chemotherapy with respect to ORR per Lugano response criteria by investigator assessment
To evaluate MK-4280A and physicians choice chemotherapy with respect to DOR per Lugano response criteria by investigator assessment
To evaluate the safety and tolerability of MK-4280A

Secondary Endpoints

Overall Survival (OS)
Objective Response Rate (ORR) per Lugano Response Criteria as Assessed by Investigator
Duration of Response (DOR) per Lugano Response Criteria as Assessed by Investigator
Number of Participants Who Experienced At Least One Adverse Event (AE)
Number of Participants Who Discontinued Study Treatment Due to an Adverse Event (AE)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Has histologically confirmed diagnosis of classical Hodgkin lymphoma (cHL) that is 2-fluorodeoxyglucose-avid (FDG-avid).
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History of hemophagocytic lymphohisticytosis.
Has an active seizure disorder that is not well controlled.
Has clinically significant (ie, active) cardiovascular disease.
Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization.

Calendar

(Last Update: 25/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/09/2022	29/09/2022	18/10/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
11/12/2024	Not aported	Not aported	29/12/2025	08/01/2026

Sponsor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Pallavi Madhusoodhan Pillai

+17325945583

pallavi.pillai@merck.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (16/03/2026)

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

Hospital Universitari Vall D Hebron

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Closed (09/03/2026)

HOSPITAL UNIVERSITARI VALL D'HEBRON

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Hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Oncology

Closed (11/03/2025)

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Hematología y Hemoterapia

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

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MÁLAGA

Hematology Department

Closed (03/03/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology Department

Medication

-
-
INTRAVENOUS INFUSION

ATC code: L01AA09 - BENDAMUSTINA
Active Principles: N/A

Experimental

MK-4280A
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

-
-
INTRAVENOUS INFUSION

ATC code: L01BC05 - GEMCITABINA
Active Principles: N/A

Experimental

No results