A clinical trial of MK-1045 in people with B-cell acute lymphoblastic leukemia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II , Fase III	240
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2025-522267-15-00 (CTIS)

Cod. Protocolo
MK-1045-005

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

Enfermedad investigada
Relapsed/refractory B-cell Acute Lymphoblastic Leukemia

Título Científico
A Phase 2/3, Randomized, Open-Label, Comparison Study of MK-1045 Versus Blinatumomab in Participants With Relapsed or Refractory CD19+ B-Cell Acute Lymphoblastic Leukemia (B-ALL)

Justificación

No aportado

Objetivo Principal

1. Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 (target dose) with respect to CR. 2. Part 1: To evaluate the safety and tolerability of the RP2D and RP2D-1 of MK-1045. 3. Part 2: To compare MK-1045 to blinatumomab with respect to CR. 4. To compare MK-1045 to blinatumomab with respect to OS.

Variables de Evaluación Primaria

Part 1: Complete remission (CR) within the first 3 treatment cycles
Part 1: Number of participants with an adverse event (AE)
Part 1: Number of participants discontinuing from study therapy due to AE
Part 2: Percentage of participants with CR within the first 3 treatment cycles
Part 2: Overall survival (OS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1: To evaluate the RP2D and RP2D-1 of MK-1084 with respect to OS.
Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 with respect to MRD negativity.
Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 with respect to CR/CRh/Cri.
Part 2: To evaluate MK-1045 compared to blinatumomab with respect to MRD negativity.
Part 2: To evaluate MK-1045 compared to blinatumomab with respect to CR/CRh.
Part 2: To evaluate MK-1045 to blinatumomab with respect to CR/CRh/CRi.
Part 2: To evaluate duration of CR.
Part 2: To evaluate duration of CR/CRh.
Part 2: To evaluate duration of CR/CRh/CRi.
Part 2: To evaluate EFS.
Part 2: To evaluate the rate of allo-HSCT following randomization.
Part 2: To evaluate the safety and tolerability of MK-1045.

Variables de Evaluación Secundaria

Part 1: OS
Part 1: Percentage of participants with minimal residual disease (MRD) negativity within the first 3 treatment cycles
Part 1: Percentage of participants with CR, complete remission with partial hematologic recovery (CRh), or complete remission with incomplete count recovery (CRi) within the first 3 treatment cycles
Part 2: Percentage of participants with MRD negativity within the first 3 treatment cycles

Part 2: Percentage of participants with CR or CRh within the first 3 treatment cycles
Part 2: Percentage of participants with CR, CRh, or CRi within the first 3 treatment cycles
Part 2: Duration of CR
Part 2: Duration of CR/CRh
Part 2: Duration of CR, CRh, or CRi
Part 2: Event free survival (EFS)
Part 2: Percentage of participants who undergo allogeneic hematopoietic stem cell transplantation (allo-HSCT)
Part 2: Percentage of participants who experienced an adverse event (AE)
Part 2: Percentage of participants who discontinued study intervention due to an AE

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

12 years of age.
Has a confirmed diagnosis of relapsed/refractory (R/R) B-precursor acute lymphoblastic leukemia (ALL) with 5% or more lymphoblasts in the bone marrow.
Has CD19+ disease, confirmed by local flow cytometry and/or immunohistochemistry testing at the time of enrollment.
Has Philadelphia-negative disease, confirmed by testing, at the time of enrollment.
Participants who have AEs due to previous anticancer therapies must have recovered to Grade 1 or baseline.

Criterios de Exclusión

Has Burkitts leukemia.
History or presence of clinically relevant central nervous system (CNS) diseases such as epilepsy, hemorrhagic/ischemic stroke, severe brain injuries, dementia, Parkinsons disease, cerebellar disease, organic brain syndrome, and psychosis.
Has active acute graft versus host disease (GvHD) or chronic GvHD. NOTE: Participants who have received CNI for GvHD within 4 weeks before the first dose of study intervention are also excluded.
History of serious cardiovascular and cerebrovascular diseases.
Has not adequately recovered from major surgery or have ongoing surgical complications.

Calendario

(Última actualización: 29/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
15/06/2026	24/06/2026	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

Merck Sharp & Dohme LLC United States

126 East Lincoln AvenueP. O. Box 2000

Contact Person

Merck Sharp

34 91 3210600

ensayos_clínicos@msd.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Clínico San Carlos

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

ceic.hcsc@salud.madrid.org

917044160

Centros

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (26/06/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (24/06/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (29/07/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medicamentos

-
-
INTRAVENOUS USE

Código ATC: L01FX07 - BLINATUMOMAB
Principios Activos: N/A

Experimental

MK-1045
SOLUTION FOR INFUSION
INTRAVENOUS USE

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Principios Activos: N/A

Experimental

-
-
INTRAVENOUS USE

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

Sin resultados

A clinical trial of MK-1045 in people with B-cell acute lymphoblastic leukemia

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II , Phase III	240
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, dose	NO

Information

Identifier
2025-522267-15-00 (CTIS)

Protocol Code
MK-1045-005

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

Investigated Disease
Relapsed/refractory B-cell Acute Lymphoblastic Leukemia

Scientific Title
A Phase 2/3, Randomized, Open-Label, Comparison Study of MK-1045 Versus Blinatumomab in Participants With Relapsed or Refractory CD19+ B-Cell Acute Lymphoblastic Leukemia (B-ALL)

Rationale

Not provided

Main Objective

1. Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 (target dose) with respect to CR. 2. Part 1: To evaluate the safety and tolerability of the RP2D and RP2D-1 of MK-1045. 3. Part 2: To compare MK-1045 to blinatumomab with respect to CR. 4. To compare MK-1045 to blinatumomab with respect to OS.

Primary Endpoints

Part 1: Complete remission (CR) within the first 3 treatment cycles
Part 1: Number of participants with an adverse event (AE)
Part 1: Number of participants discontinuing from study therapy due to AE
Part 2: Percentage of participants with CR within the first 3 treatment cycles
Part 2: Overall survival (OS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1: To evaluate the RP2D and RP2D-1 of MK-1084 with respect to OS.
Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 with respect to MRD negativity.
Part 1: To evaluate the RP2D and RP2D-1 of MK-1045 with respect to CR/CRh/Cri.
Part 2: To evaluate MK-1045 compared to blinatumomab with respect to MRD negativity.
Part 2: To evaluate MK-1045 compared to blinatumomab with respect to CR/CRh.
Part 2: To evaluate MK-1045 to blinatumomab with respect to CR/CRh/CRi.
Part 2: To evaluate duration of CR.
Part 2: To evaluate duration of CR/CRh.
Part 2: To evaluate duration of CR/CRh/CRi.
Part 2: To evaluate EFS.
Part 2: To evaluate the rate of allo-HSCT following randomization.
Part 2: To evaluate the safety and tolerability of MK-1045.

Secondary Endpoints

Part 1: OS
Part 1: Percentage of participants with minimal residual disease (MRD) negativity within the first 3 treatment cycles
Part 1: Percentage of participants with CR, complete remission with partial hematologic recovery (CRh), or complete remission with incomplete count recovery (CRi) within the first 3 treatment cycles
Part 2: Percentage of participants with MRD negativity within the first 3 treatment cycles

Part 2: Percentage of participants with CR or CRh within the first 3 treatment cycles
Part 2: Percentage of participants with CR, CRh, or CRi within the first 3 treatment cycles
Part 2: Duration of CR
Part 2: Duration of CR/CRh
Part 2: Duration of CR, CRh, or CRi
Part 2: Event free survival (EFS)
Part 2: Percentage of participants who undergo allogeneic hematopoietic stem cell transplantation (allo-HSCT)
Part 2: Percentage of participants who experienced an adverse event (AE)
Part 2: Percentage of participants who discontinued study intervention due to an AE

Temporary moments of secondary assessment

Not provided

Inclusion criteria

12 years of age.
Has a confirmed diagnosis of relapsed/refractory (R/R) B-precursor acute lymphoblastic leukemia (ALL) with 5% or more lymphoblasts in the bone marrow.
Has CD19+ disease, confirmed by local flow cytometry and/or immunohistochemistry testing at the time of enrollment.
Has Philadelphia-negative disease, confirmed by testing, at the time of enrollment.
Participants who have AEs due to previous anticancer therapies must have recovered to Grade 1 or baseline.

Exclusion criteria

Has Burkitts leukemia.
History or presence of clinically relevant central nervous system (CNS) diseases such as epilepsy, hemorrhagic/ischemic stroke, severe brain injuries, dementia, Parkinsons disease, cerebellar disease, organic brain syndrome, and psychosis.
Has active acute graft versus host disease (GvHD) or chronic GvHD. NOTE: Participants who have received CNI for GvHD within 4 weeks before the first dose of study intervention are also excluded.
History of serious cardiovascular and cerebrovascular diseases.
Has not adequately recovered from major surgery or have ongoing surgical complications.

Calendar

(Last Update: 29/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
15/06/2026	24/06/2026	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

Merck Sharp & Dohme LLC United States

126 East Lincoln AvenueP. O. Box 2000

Contact Person

Merck Sharp

34 91 3210600

ensayos_clínicos@msd.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Clínico San Carlos

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

ceic.hcsc@salud.madrid.org

917044160

Sites

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Active (26/06/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (24/06/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (29/07/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medication

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INTRAVENOUS USE

ATC code: L01FX07 - BLINATUMOMAB
Active Principles: N/A

Experimental

MK-1045
SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

-
-
INTRAVENOUS USE

ATC code: L04AC07 - TOCILIZUMAB
Active Principles: N/A

Experimental

No results