A trial to learn how safe AZD4512 is and how it works in the bodies of people with B-cell acute lymphoblastic leukemia (B-ALL)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	70
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2025-522372-93-00 (CTIS)

Cod. Protocolo
ALLight D9891C00001

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
B-cell acute lymphoblastic leukemia (B-ALL)

Título Científico
A modular Phase I/II, open-label, multi-center study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary efficacy of AZD4512 monotherapy or in combination with anticancer agent(s) in participants with Acute Lymphoblastic Leukemia

Justificación

No aportado

Objetivo Principal

Module 1 Dose Escalation: To assess the safety and tolerability of AZD4512 in participants with R/R B-ALL [Ph(-) and Ph(+)] as defined by NCCN guidelines
Module 1 Dose Escalation: To identify the MTD and/or doses of AZD4512 for subsequent evaluation in Module 2
Module 2 Dose Optimization:To evaluate the efficacy and determine the RP2D of AZD4512 in participants with R/R Ph(-) B-ALL based on NCCN response criteria
Module 2 Dose Optimization: To assess the safety and tolerability of AZD4512 in participants with R/R Ph(-) B-ALL

Variables de Evaluación Primaria

Module 1 Dose Escalation: Safety and Tolerability of AZD4512 -Assessment of DLT -Assessment of TEAEs/TRAEs/SAEs -Interruptions, modifications, delays and discontinuations -Clinically significant changes from baseline
Module 1 Dose Escalation: Determine the MTD and/or doses to explore in Module 2
Module 2 Dose Optimization: Antitumour activity and determine the RP2D of AZD4512 -Response Rate: ORR (CR/CRh)
Module 2 Dose Optimization:Safety and Tolerability of AZD4512 -Assessment of TEAEs/TRAEs/SAEs -Interruptions, modifications, delays and discontinuations -Clinically significant changes from baseline

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Module 1 Dose Escalation: To characterize the PK of AZD4512 as monotherapy
Module 1 Dose Escalation: To determine the immunogenicity of AZD4512 as monotherapy
Module 1 Dose Escalation: To evaluate the preliminary efficacy of AZD4512 as monotherapy in participants with R/R B-ALL [Ph(-) and Ph(+)] as defined by NCCN guidelines
Module 2 Dose Optimization: To evaluate the efficacy of AZD4512 based on NCCN response criteria
Module 2 Dose Optimization: To evaluate the impact of AZD4512 on MRD by NGS [central]
Module 2 Dose Optimization: To characterize the PK of AZD4512 as monotherapy
Module 2 Dose Optimization: To determine the immunogenicity of AZD4512 as monotherapy

Variables de Evaluación Secundaria

Module 1 Dose Escalation: Characterize AZD4512 PK as monotherapy
Module 1 Dose Escalation: Immunogenicity as monotherapy -ADA development
Module 1 Dose Escalation: Preliminary Antitumour Activity of AZD4512 -Response Rate: ORR (CR/CRh), CR and

CRc rate, TTR, DoR, EFS, OS, subsequent HSCT
Module 2 Dose Optimization: Antitumour Activity of AZD4512 -Response Rate: CR and CRc rate, TTR, DoR, EFS, OS, subsequent HSCT
Module 2 Dose Optimization: Effect of AZD4512 on MRD (NGS) -MRD-negative CR rate, CR/CRh (ORR), CRc (CR/CRi/CRh) rate
Module 2 Dose Optimization: PK of AZD4512 as monotherapy
Module 2 Dose Optimization: Immunogenicity as monotherapy -ADA development

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Age: 16 years old in Module 1 (US only: 18year) 12 years old in Module 2 2. Diagnosis: Diagnosis of B-ALL WHO (WHO-HAEM5) Participants must have relapsed or refractory B-ALL (relapsed defined as bone marrow blasts > 5% or reappearance of blasts in PB) - Module 1 (DE): Ph(-) B-ALL and Ph(+) B-ALL R/R - Backfill of Module 1 and Module 2 (DO): R/R Ph(-) B-ALL (BM blasts >5%) 3. Performance status (ECOG 2; KPS 50; LPS 50) 4. Peripheral lymphoblast count < 10,000/µL (may receive cytoreduction prior to C1D1 per protocol-specified criteria) 5. At least 2 prior therapies with refractoriness or relapse, or 1 prior therapy with refractoriness or relapse and no standard options available -Ph+ B-ALL (Module 1 DE only): intolerant to or have contraindications to TKI therapy or R/R disease despite treatment with at least 2 prior TKIs or at least one 3rd generation TKI 6. Prior DLI >4 weeks, prior cell therapy or autoHSCT >8 weeks, alloHSCT >12 weeks

Criterios de Exclusión

1. Burkitt lymphoma and leukemia 2. Isolated extramedullary disease; Active testicular or CNS (> CNS1) involvement 3. Unresolved non-heme toxicities Grade 2 (except alopecia, stable Grade 2 neuropathy, vitiligo, endocrine disorders controlled with therapy) 4. History of drug-induced non-infectious ILD/pneumonitis requiring oral or IV steroids or supplemental oxygen or where suspected ILD/pneumonitis cannot be ruled out by imaging at screening 5. Prior/concomitant therapy -Cytotoxic treatment within 14 days (except ALL maintenance medications or cytoreduction) -Biologic (immuno-oncology) treatment within 28 days or 5 half-lives (whichever is shorter) -Non-CNS radiation within 2 weeks & CNS radiation within 4 weeks -Medications known to prolong QTc and/or associated with Torsades de Pointes within 5 half-lives -Strong inhibitors of CYP 3A4 within 14 days or 5 half-lives (whichever is longer) -Investigational agents or study interventions in the last 30 days or 5 half-lives prior to the first dose of AZD4512 whichever is longer. If the investigational product is an agent to treat B-ALL and meets the modality criteria, then a specific washout period must be adhered to instead.

Calendario

(Última actualización: 10/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/11/2025	13/01/2026	19/01/2026	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

AstraZeneca AB Sweden

-

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de Cantabria

Edificio IFIMAV 3ª Planta Avda Cardenal Herrera Oria s/n 39011 Santander

ceim@idival.org

942315514

Centros

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Servicio de Hematologia

Activo (13/01/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematologia

Activo (22/01/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematologia

Activo (05/02/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematologia

Medicamentos

AZD4512
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

A trial to learn how safe AZD4512 is and how it works in the bodies of people with B-cell acute lymphoblastic leukemia (B-ALL)

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	70
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2025-522372-93-00 (CTIS)

Protocol Code
ALLight D9891C00001

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
B-cell acute lymphoblastic leukemia (B-ALL)

Scientific Title
A modular Phase I/II, open-label, multi-center study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary efficacy of AZD4512 monotherapy or in combination with anticancer agent(s) in participants with Acute Lymphoblastic Leukemia

Rationale

Not provided

Main Objective

Module 1 Dose Escalation: To assess the safety and tolerability of AZD4512 in participants with R/R B-ALL [Ph(-) and Ph(+)] as defined by NCCN guidelines
Module 1 Dose Escalation: To identify the MTD and/or doses of AZD4512 for subsequent evaluation in Module 2
Module 2 Dose Optimization:To evaluate the efficacy and determine the RP2D of AZD4512 in participants with R/R Ph(-) B-ALL based on NCCN response criteria
Module 2 Dose Optimization: To assess the safety and tolerability of AZD4512 in participants with R/R Ph(-) B-ALL

Primary Endpoints

Module 1 Dose Escalation: Safety and Tolerability of AZD4512 -Assessment of DLT -Assessment of TEAEs/TRAEs/SAEs -Interruptions, modifications, delays and discontinuations -Clinically significant changes from baseline
Module 1 Dose Escalation: Determine the MTD and/or doses to explore in Module 2
Module 2 Dose Optimization: Antitumour activity and determine the RP2D of AZD4512 -Response Rate: ORR (CR/CRh)
Module 2 Dose Optimization:Safety and Tolerability of AZD4512 -Assessment of TEAEs/TRAEs/SAEs -Interruptions, modifications, delays and discontinuations -Clinically significant changes from baseline

Temporary moments of secondary assessment

Not provided

Secondary Objective

Module 1 Dose Escalation: To characterize the PK of AZD4512 as monotherapy
Module 1 Dose Escalation: To determine the immunogenicity of AZD4512 as monotherapy
Module 1 Dose Escalation: To evaluate the preliminary efficacy of AZD4512 as monotherapy in participants with R/R B-ALL [Ph(-) and Ph(+)] as defined by NCCN guidelines
Module 2 Dose Optimization: To evaluate the efficacy of AZD4512 based on NCCN response criteria
Module 2 Dose Optimization: To evaluate the impact of AZD4512 on MRD by NGS [central]
Module 2 Dose Optimization: To characterize the PK of AZD4512 as monotherapy
Module 2 Dose Optimization: To determine the immunogenicity of AZD4512 as monotherapy

Secondary Endpoints

Module 1 Dose Escalation: Characterize AZD4512 PK as monotherapy
Module 1 Dose Escalation: Immunogenicity as monotherapy -ADA development
Module 1 Dose Escalation: Preliminary Antitumour Activity of AZD4512 -Response Rate: ORR (CR/CRh), CR and

CRc rate, TTR, DoR, EFS, OS, subsequent HSCT
Module 2 Dose Optimization: Antitumour Activity of AZD4512 -Response Rate: CR and CRc rate, TTR, DoR, EFS, OS, subsequent HSCT
Module 2 Dose Optimization: Effect of AZD4512 on MRD (NGS) -MRD-negative CR rate, CR/CRh (ORR), CRc (CR/CRi/CRh) rate
Module 2 Dose Optimization: PK of AZD4512 as monotherapy
Module 2 Dose Optimization: Immunogenicity as monotherapy -ADA development

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Age: 16 years old in Module 1 (US only: 18year) 12 years old in Module 2 2. Diagnosis: Diagnosis of B-ALL WHO (WHO-HAEM5) Participants must have relapsed or refractory B-ALL (relapsed defined as bone marrow blasts > 5% or reappearance of blasts in PB) - Module 1 (DE): Ph(-) B-ALL and Ph(+) B-ALL R/R - Backfill of Module 1 and Module 2 (DO): R/R Ph(-) B-ALL (BM blasts >5%) 3. Performance status (ECOG 2; KPS 50; LPS 50) 4. Peripheral lymphoblast count < 10,000/µL (may receive cytoreduction prior to C1D1 per protocol-specified criteria) 5. At least 2 prior therapies with refractoriness or relapse, or 1 prior therapy with refractoriness or relapse and no standard options available -Ph+ B-ALL (Module 1 DE only): intolerant to or have contraindications to TKI therapy or R/R disease despite treatment with at least 2 prior TKIs or at least one 3rd generation TKI 6. Prior DLI >4 weeks, prior cell therapy or autoHSCT >8 weeks, alloHSCT >12 weeks

Exclusion criteria

1. Burkitt lymphoma and leukemia 2. Isolated extramedullary disease; Active testicular or CNS (> CNS1) involvement 3. Unresolved non-heme toxicities Grade 2 (except alopecia, stable Grade 2 neuropathy, vitiligo, endocrine disorders controlled with therapy) 4. History of drug-induced non-infectious ILD/pneumonitis requiring oral or IV steroids or supplemental oxygen or where suspected ILD/pneumonitis cannot be ruled out by imaging at screening 5. Prior/concomitant therapy -Cytotoxic treatment within 14 days (except ALL maintenance medications or cytoreduction) -Biologic (immuno-oncology) treatment within 28 days or 5 half-lives (whichever is shorter) -Non-CNS radiation within 2 weeks & CNS radiation within 4 weeks -Medications known to prolong QTc and/or associated with Torsades de Pointes within 5 half-lives -Strong inhibitors of CYP 3A4 within 14 days or 5 half-lives (whichever is longer) -Investigational agents or study interventions in the last 30 days or 5 half-lives prior to the first dose of AZD4512 whichever is longer. If the investigational product is an agent to treat B-ALL and meets the modality criteria, then a specific washout period must be adhered to instead.

Calendar

(Last Update: 10/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/11/2025	13/01/2026	19/01/2026	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

AstraZeneca AB Sweden

-

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm de Cantabria

Edificio IFIMAV 3ª Planta Avda Cardenal Herrera Oria s/n 39011 Santander

ceim@idival.org

942315514

Sites

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Servicio de Hematologia

Active (13/01/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematologia

Active (22/01/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematologia

Active (05/02/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematologia

Medication

AZD4512

SOLUTION FOR INJECTION/INFUSION

IV INFUSION

-

Active Principles: N/A

Experimental

No results