

A trial to learn if AZD0486 alone or with other anticancer drugs is safe and works in adults with certain blood cancers

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase I , Fase II

Participantes esperados

246

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética, dosis

Terapia avanzada

NO

Información

Identificador

2024-515034-33-00 (CTIS)

Cod. Protocolo

D7407C00001

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Chronic Lymphocytic Leukaemia
Large B-Cell Lymphoma
Mantle Cell Lymphoma
Small Lymphocytic Lymphoma

Título Científico

A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate the Safety and Efficacy of AZD0486 Monotherapy

or in Combination with Other Anticancer Agents in Participants with Mature B-Cell Malignancies
Substudy 1: Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma
Substudy 2: Mantle Cell Lymphoma
Substudy 3: Large B-Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To assess safety and tolerability and determine the RP2D (recommended Phase II dose) of surovatamig (administered as IV or SC) as monotherapy and in combination with other anticancer agents across mature B-cell malignancies

Variables de Evaluación Primaria

Incidence, nature and severity of AEs/SAEs based on NCI CTCAE v5.0/ASTCT criteria; changes in laboratory data, and vital signs compared with baseline
Incidence of Dose Limiting Toxicity (DLTs)
Incidence and severity of AESIs
Incidence and nature of study drug discontinuation, dose reduction and dose delay due to AEs

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

All sub- studies: Age 18 years Sub- study 2, Cohort 2A and Cohort 2C: Relapsed or Progressed after 2 or more prior systemic therapy for MCL including BTKi Sub-study 3A: Previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms OR Relapsed or refractory B-cell NHL after at least 1 prior lines of systemic therapy, Histologically confirmed according to WHO 2022 classification (excluding some B-NHL subtypes) Sub-study 3: LVEF >50% Sub-study 3A: IPI 2-5 for participants with untreated LBCL diagnoses Sub-study 3: At least 1 measurable site as per Lugano Sub-study 1B: Contraception during treatment and until at least x days after the last dose of Surovatamig and until 2 days after the last dose of acalabrutinib, whichever is longer. All sub- studies: ECOG performance status 0 to 2 Sub-study 3: Contraception until x days after the last dose of surovatamig, 4 months after the last dose of vincristine, and 6 months after the last dose of cyclophosphamide or doxorubicin, (or as required by local prescribing information) whichever is longer. All sub-studies: Contraception during treatment and at least x days after final dose All sub- studies: Confirmed CD19 expression if prior anti-CD19 therapy Sub-study 1, Cohort 1A and Cohort 1C: at least 2 prior lines of systemic therapy for CLL/SLL including treatment with a BTKi and BCL2i Sub-study 1: CLL/SLL diagnosis and meets iwCLL criteria for treatment Sub-study 1: SLL: at least 1 measurable site per Lugano Sub-study 1: Absolute lymphocytes <25,000 cells/mcl Sub study 3B: Histologically confirmed diagnosis of previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms Sub study 3B: For all participants: IPI score of 2 to 5. Sub-study 3: Participant must be no older than 79 years of age at the time of signing ICF Sub-study 1, Cohort 1B: at least 1 prior line of therapy and BTKi sensitive Sub-study 2: MCL diagnosis per WHO Sub-study 3: Absolute lymphocytes count of $< 5 \times 10^9$ cells/L Sub-study 3: Haemoglobin 9 g/dL Sub-study 2: Clinical Stage II, III, or IV per Ann Arbor classification Sub-study 2: At least 1 measurable site per Lugano Sub-study 2: ALC < 25,000 cells/mcl

Criterios de Exclusión

All sub- studies: CNS lymphoma Sub-study 3: Cumulative dose of anthracycline > 150 mg/m² All sub- studies: Major Surgical procedure within 14 days before the first dose of study drug All sub- studies: Clinically significant CV disease All sub- studies: Unresolved non-haematological Grade 2 AEs (NCI CTCAE V5.0) from prior anticancer therapy (except alopecia or fatigue) All sub-studies: Any anticancer systemic therapy within 5 half-lives or 21 days (whichever is shorter) prior to Cycle 1 Day 1 Prior allogenic HSCT or solid organ transplantation within 24 weeks of starting Cycle 1 Day 1 All sub-studies: Radiation therapy within 28 days of Cycle 1 Day 1 All sub-studies: Prior CAR-T therapy or auto-HSCT within 12 weeks or prior TCE within 8 weeks of Cycle 1 Day 1 All sub-studies: Prior Grade 3 CRS or ICANS event Sub-study 1: CLL transformation to more aggressive lymphoma All sub-studies: Active, significant, or uncontrolled infection or autoimmune disease requiring systemic therapy which places participant at unacceptable risk if he/she were to participate in the study Sub-study 1, Cohort 1B: bleeding diathesis, treatment with strong CYP3A inhibitor or inducer, history of ICH or stroke within 24 weeks, GI malabsorption, receiving vitamin K antagonist Sub-study 2 Exclusion Criteria Refer to Section 5.2 of the Master Protocol. Sub-study 3: Mediastinal grey-zone lymphoma, Burkitt, Richters transformation, primary effusion LBCL

Calendario

(Última actualización: 05/06/2026)

Autorización 07/01/2025	Inicio de Ensayo 05/03/2025	Inclusión Primer Paciente 01/04/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 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

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Centros

Activo (04/06/2025)	Complejo Hospitalario Universitario De Santiago Santiago De Compostela CORUÑA 7003: Hematologícuta	Hospital Clinic De Barcelona Barcelona BARCELONA 7004: Hematologícuta
Activo (10/03/2025)	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID 7001: Hematologícuta y Hemoterapia	Hospital Universitario Ramon Y Cajal Madrid MADRID 7006: Hematologícuta
Activo (26/02/2025)	Hospital Universitario Y Politecnico La Fe Valencia VALENCIA 7005: Hematologícuta	University Hospital Son Espases Palma BALEARES 7002: Hematologia

Medicamentos

-
-
ORAL USE

Código ATC: H02AB07 - PREDNISONA
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Principios Activos: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

-
-
ORAL USE

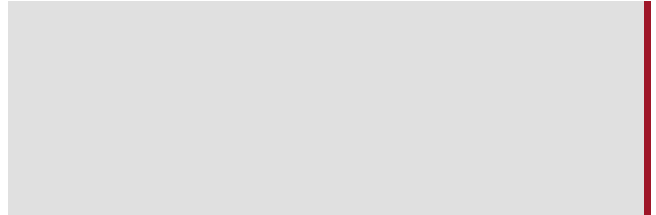
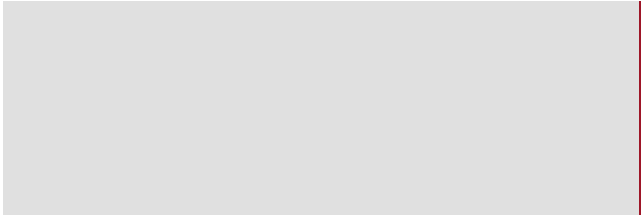
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Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01XC02 - RITUXIMAB
Principios Activos: N/A

Experimental



-
-

INTRAVENOUS

Código ATC: L01CA02 - VINCRIPTINA
Principios Activos: N/A

Experimental

-
-

INTRAVENOUS

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A

Experimental

-
-

INTRAVENOUS

Código ATC: L01DB01 - DOXORUBICINA
Principios Activos: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A

Experimental

-
-

INTRAVENOUS

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Sin resultados

A trial to learn if AZD0486 alone or with other anticancer drugs is safe and works in adults with certain blood cancers

State
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase I , Phase II

Expected Participants
246

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics, dose

Advanced therapy
NO

Information

Identifier
2024-515034-33-00 (CTIS)

Protocol Code
D7407C00001

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Chronic Lymphocytic Leukaemia
Large B-Cell Lymphoma
Mantle Cell Lymphoma
Small Lymphocytic Lymphoma

Scientific Title
A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate the Safety and Efficacy of AZD0486 Monotherapy

or in Combination with Other Anticancer Agents in Participants with Mature B-Cell Malignancies
Substudy 1: Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma
Substudy 2: Mantle Cell Lymphoma
Substudy 3: Large B-Cell Lymphoma

Rationale

Not provided

Main Objective

To assess safety and tolerability and determine the RP2D (recommended Phase II dose) of surovatamig (administered as IV or SC) as monotherapy and in combination with other anticancer agents across mature B-cell malignancies

Primary Endpoints

Incidence, nature and severity of AEs/SAEs based on NCI CTCAE v5.0/ASTCT criteria; changes in laboratory data, and vital signs compared with baseline
Incidence of Dose Limiting Toxicity (DLTs)
Incidence and severity of AESIs
Incidence and nature of study drug discontinuation, dose reduction and dose delay due to AEs

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

All sub- studies: Age 18 years Sub- study 2, Cohort 2A and Cohort 2C: Relapsed or Progressed after 2 or more prior systemic therapy for MCL including BTKi Sub-study 3A: Previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms OR Relapsed or refractory B-cell NHL after at least 1 prior lines of systemic therapy, Histologically confirmed according to WHO 2022 classification (excluding some B-NHL subtypes) Sub-study 3: LVEF >50% Sub-study 3A: IPI 2-5 for participants with untreated LBCL diagnoses Sub-study 3: At least 1 measurable site as per Lugano Sub-study 1B: Contraception during treatment and until at least x days after the last dose of Surovatamig and until 2 days after the last dose of acalabrutinib, whichever is longer. All sub- studies: ECOG performance status 0 to 2 Sub-study 3: Contraception until x days after the last dose of surovatamig, 4 months after the last dose of vincristine, and 6 months after the last dose of cyclophosphamide or doxorubicin, (or as required by local prescribing information) whichever is longer. All sub-studies: Contraception during treatment and at least x days after final dose All sub- studies: Confirmed CD19 expression if prior anti-CD19 therapy Sub-study 1, Cohort 1A and Cohort 1C: at least 2 prior lines of systemic therapy for CLL/SLL including treatment with a BTKi and BCL2i Sub-study 1: CLL/SLL diagnosis and meets iwCLL criteria for treatment Sub-study 1: SLL: at least 1 measurable site per Lugano Sub-study 1: Absolute lymphocytes <25,000 cells/mcl Sub study 3B: Histologically confirmed diagnosis of previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms Sub study 3B: For all participants: IPI score of 2 to 5. Sub-study 3: Participant must be no older than 79 years of age at the time of signing ICF Sub-study 1, Cohort 1B: at least 1 prior line of therapy and BTKi sensitive Sub-study 2: MCL diagnosis per WHO Sub-study 3: Absolute lymphocytes count of $< 5 \times 10^9$ cells/L Sub-study 3: Haemoglobin 9 g/dL Sub-study 2: Clinical Stage II, III, or IV per Ann Arbor classification Sub-study 2: At least 1 measurable site per Lugano Sub-study 2: ALC < 25,000 cells/mcl

Exclusion criteria

All sub- studies: CNS lymphoma Sub-study 3: Cumulative dose of anthracycline > 150 mg/m² All sub- studies: Major Surgical procedure within 14 days before the first dose of study drug All sub- studies: Clinically significant CV disease All sub- studies: Unresolved non-haematological Grade 2 AEs (NCI CTCAE V5.0) from prior anticancer therapy (except alopecia or fatigue) All sub-studies: Any anticancer systemic therapy within 5 half-lives or 21 days (whichever is shorter) prior to Cycle 1 Day 1 Prior allogenic HSCT or solid organ transplantation within 24 weeks of starting Cycle 1 Day 1 All sub-studies: Radiation therapy within 28 days of Cycle 1 Day 1 All sub-studies: Prior CAR-T therapy or auto-HSCT within 12 weeks or prior TCE within 8 weeks of Cycle 1 Day 1 All sub-studies: Prior Grade 3 CRS or ICANS event Sub-study 1: CLL transformation to more aggressive lymphoma All sub-studies: Active, significant, or uncontrolled infection or autoimmune disease requiring systemic therapy which places participant at unacceptable risk if he/she were to participate in the study Sub-study 1, Cohort 1B: bleeding diathesis, treatment with strong CYP3A inhibitor or inducer, history of ICH or stroke within 24 weeks, GI malabsorption, receiving vitamin K antagonist Sub-study 2 Exclusion Criteria Refer to Section 5.2 of the Master Protocol. Sub-study 3: Mediastinal grey-zone lymphoma, Burkitt, Richters transformation, primary effusion LBCL

Calendar

(Last Update: 05/06/2026)

Authorization 07/01/2025	Start of Trial 05/03/2025	First patient inclusion 01/04/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

AstraZeneca AB Sweden

-

Contact Person

AstraZeneca Clinical Study Information Center

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Information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (04/06/2025)	Complejo Hospitalario Universitario De Santiago Santiago De Compostela CORUÑA 7003: Hematologícuta	Hospital Clinic De Barcelona Barcelona BARCELONA 7004: Hematologícuta
Active (10/03/2025)	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID 7001: Hematologícuta y Hemoterapia	Hospital Universitario Ramon Y Cajal Madrid MADRID 7006: Hematologícuta
Active (26/02/2025)	Hospital Universitario Y Politecnico La Fe Valencia VALENCIA 7005: Hematologícuta	University Hospital Son Espases Palma BALEARES 7002: Hematologia

Medication

-
-
ORAL USE

ATC code: H02AB07 - PREDNISONA
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A

Experimental

-
-
ORAL USE

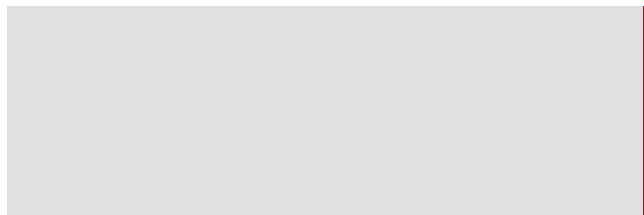
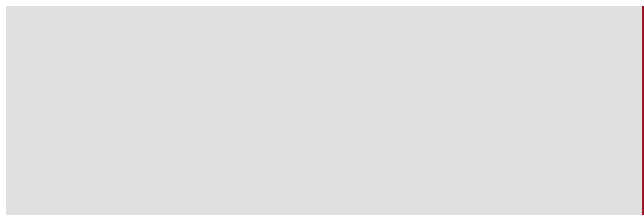
ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01XC02 - RITUXIMAB
Active Principles: N/A

Experimental



-
-
INTRA VENOUS

ATC code: L01CA02 - VINCRISTINA
Active Principles: N/A
Experimental

-
-
INTRA VENOUS

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A
Experimental

-
-
INTRA VENOUS

ATC code: L01DB01 - DOXORUBICINA
Active Principles: N/A
Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A
Experimental

-
-
INTRA VENOUS

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A
Experimental

No results