A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP 196 in Combination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	323
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, eficacia, farmacocinética	NO

Información

Identificador
2023-509348-84-00 (CTIS)

Cod. Protocolo
ACE-CL-007

Transicionado 2014-005582-73

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

Enfermedad investigada
Chronic Lymphocytic Leukemia

Título Científico
A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP 196 in Combination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated

Chronic Lymphocytic Leukemia

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of obinutuzumab in combination with chlorambucil (Arm A) compared with acalabrutinib in combination with obinutuzumab (Arm B), based on IRC assessment of PFS per IWCLL 2008 criteria, in subjects with previously untreated CLL.

Variables de Evaluación Primaria

The primary endpoint of the study is PFS as assessed by IRC review per IWCLL 2008 criteria. The primary analysis is a comparison of PFS between Arm A and Arm B.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of Arm A versus acalabrutinib monotherapy based on IRC assessment of PFS per IWCLL 2008 criteria. To compare Arm A versus Arm B and Arm A versus Arm C in terms of: IRC-assessed objective response rate (ORR) per IWCLL 2008 criteria; Time to next treatment (TTNT) (defined as the time from randomization to institution of non-protocol specified treatment for CLL); Overall survival (OS);

Variables de Evaluación Secundaria

"Efficacy: The first secondary endpoint is a comparison of IRC-assessed PFS between Arm A and Arm C. Other secondary endpoints are as follows and compare Arm A versus Arm B and Arm A versus Arm C OS. Safety: Frequency, severity, and relatedness of adverse events. Frequency of adverse events requiring discontinuation of study drug or dose reductions. Change in laboratory assessments. "
Efficacy: The first secondary endpoint is a comparison of IRC-assessed PFS between Arm A and Arm C. Other secondary endpoints are as follows and compare Arm A versus Arm B and Arm A versus Arm C OS. Safety: Frequency, severity, and relatedness of adverse events. Frequency of adverse events requiring discontinuation of study drug or dose reductions. Change in laboratory assessments.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

" Men and women 65 years of age, or > 18 and < 65 years of age provided that they meet at least one of the following criteria: o Creatinine clearance 30 to 69 mL/min using the Cockcroft-Gault equation. o A score higher than 6 on the Cumulative Illness Rating Scale-Geriatric (CIRS-G). ECOG performance status of 0, 1, or 2. Diagnosis of CD20+ CLL that meets published diagnostic criteria (Hallek 2008) Active disease meeting 1 of the following IWCLL 2008 criteria for requiring treatment: o Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia (hemoglobin < 10 g/dL) and/or thrombocytopenia (platelets < 100,000/L). o Massive (ie, 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. o Massive nodes (ie, 10 cm in the longest diameter), progressive, or symptomatic lymphadenopathy. o Progressive lymphocytosis with an increase of > 50% over a 2-month period or a lymphocyte doubling time (LDT) of < 6 months. LDT may be obtained by linear regression extrapolation of absolute lymphocyte counts (ALC) obtained at intervals of 2 weeks over an observation period of 2 to 3 months. In subjects with initial blood lymphocyte counts of < 30 x 10^9/L (30,000/L), LDT should not be used as a single parameter to define indication for treatment. In addition, factors contributing to lymphocytosis or lymphadenopathy other than CLL (eg, infections) should be excluded. o Autoimmune anemia and/or thrombocytopenia that is poorly responsive to standard therapy. o Constitutional symptoms documented in the subject's chart with supportive objective measures, as appropriate, defined as 1 of the following disease-related symptoms or signs: - Unintentional weight loss 10% within the previous 6 months before Screening. - Significant fatigue (ie, ECOG performance status 2; inability to work or perform usual activities). - Fevers higher than 100.5°F or 38.0°C for 2 or more weeks before Screening without evidence of infection. - Night sweats for > 1 month before Screening without evidence of infection. Meet the following laboratory parameters: o Absolute neutrophil count 750 cells/L (0.75 x 10^9/L) or 500 cells/L (0.50 x 10^9/L) in subjects with documented bone marrow involvement and independent of growth factor support 7 days before assessment. o Platelet count 50,000 cells/L (50 x 10^9/L), or 30,000 cells/L (30 x 10^9/L) in subjects with documented bone marrow involvement, and without transfusion support 7 days before assessment. Subjects with transfusion-dependent thrombocytopenia are excluded. o Serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 3.0 x upper limit of normal (ULN). o Total bilirubin 1.5 x ULN. o Estimated creatinine clearance (ie, estimated glomerular filtration rate [eGFR] using Cockcroft-Gault) 30 mL/min. Able to receive all outpatient treatment, all laboratory monitoring, and all radiologic evaluations. Women who are sexually active and can bear children must agree to use highly effective forms of contraception while on the study and for 2 days after the last dose of acalabrutinib or 18 months after the last dose of obinutuzumab in combination with chlorambucil, whichever is longer. Men who are sexually active and can beget children must agree to use highly effective forms of contraception during the study and for 90 days after the last dose of obinutuzumab or chlorambucil, whichever is later. Men must agree to refrain from sperm donation during the study and for 90 days after the last dose of obinutuzumab or chlorambucil, whichever is later. Are willing and able to adhere to the study visit schedule, understand and comply with other protocol requirements, and provide written informed consent and authorization to use protected health information." 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higher than 100.5°F or 38.0°C for 2 or more weeks before Screening without evidence of infection. - Night sweats for > 1 month before Screening without evidence of infection. Meet the following laboratory parameters: o Absolute neutrophil count 750 cells/L (0.75 x 10^9/L) or 500 cells/L (0.50 x 10^9/L) in subjects with documented bone marrow involvement and independent of growth factor support 7 days before assessment. o Platelet count 50,000 cells/L (50 x 10^9/L), or 30,000 cells/L (30 x 10^9/L) in subjects with documented bone marrow involvement, and without transfusion support 7 days before assessment. Subjects with transfusion-dependent thrombocytopenia are excluded. o Serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 3.0 x upper limit of normal (ULN). o Total bilirubin 1.5 x ULN. o Estimated creatinine clearance (ie, estimated glomerular filtration rate [eGFR] using Cockcroft-Gault) 30 mL/min. Able to receive all outpatient treatment, all laboratory monitoring, and all radiologic evaluations. Women who are sexually active and can bear children must agree to use highly effective forms of contraception while on the study and for 2 days after the last dose of acalabrutinib or 18 months after the last dose of obinutuzumab in combination with chlorambucil, whichever is longer. Men who are sexually active and can beget children must agree to use highly effective forms of contraception during the study and for 90 days after the last dose of obinutuzumab or chlorambucil, whichever is later. Men must agree to refrain from sperm donation during the study and for 90 days after the last dose of obinutuzumab or chlorambucil, whichever is later. Are willing and able to adhere to the study visit schedule, understand and comply with other protocol requirements, and provide written informed consent and authorization to use protected health information.

Criterios de Exclusión

" Any prior systemic treatment for CLL (note: Prior localized radiotherapy is allowed). Known central nervous system (CNS) lymphoma or leukemia. Known prolymphocytic leukemia or history of, or currently suspected, Richter's syndrome. Missing or incomplete documentation of FISH results reflecting the presence or absence of 17p del and the percentage of cells with the deletion in subject records before randomization. Uncontrolled autoimmune hemolytic anemia (AIHA) or idiopathic thrombocytopenic purpura (ITP) defined as declining hemoglobin or platelet count secondary to autoimmune destruction within the screening period or requirement for high doses of steroids (> 20mg daily of prednisone daily or equivalent). Corticosteroid use > 20 mg within 1 week before first dose of study drug, except as indicated for other medical conditions such as inhaled steroid for asthma, topical steroid use, or as premedication for administration of study drug or contrast. For example, subjects requiring steroids at daily doses > 20 mg prednisone equivalent systemic exposure daily, or those who are administered steroids for leukemia control or white blood cell count (WBC) lowering are excluded"

Calendario

(Última actualización: 17/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/11/2015	31/03/2016	No aportado	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
07/12/2016	No aportado	No aportado	30/09/2025	04/09/2026

Promotor

Acerta Pharma B.V. Netherlands

Kloosterstraat 9

Contact Person

Carla Hartman

0031615465931

carla.hartman@acerta-pharma.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Fundacio de Gestio Sanitaria Hospital de la Santa Creu i Sant Pau

C/ Sant Quintí, 77-79. Planta 1a. Despacho 95 08041 Barcelona

ceimsantpau@santpau.cat

935537813

Centros

Cerrado (13/06/2016)

CLINICA UNIVERSIDAD DE NAVARRA

PAMPLONA/IRUÑA

NAVARRA

Servicio de Hematología

Cerrado (25/02/2026)

HOSPITAL DE LA SANTA CREU I SANT PAU

BARCELONA

BARCELONA

Servicio de Hematología

Cerrado (30/03/2017)

HOSPITAL GENERAL UNIVERSITARIO J.M. MORALES MESEGUER

MURCIA

MURCIA

Servicio de Hematología

Cerrado (15/03/2017)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

MADRID

MADRID

Servicio de Hematología

Cerrado (09/02/2026)

HOSPITAL UNIVERSITARIO INFANTA LEONOR (*)

MADRID

MADRID

Servicio de Hematología

Cerrado (14/06/2022)

HOSPITAL UNIVERSITARIO MARQUÉS DE VALDECILLA

SANTANDER

CANTABRIA

Servicio de Hematología

Cerrado (30/01/2026)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

MAJADAHONDA

MADRID

Servicio de Hematología

Cerrado (12/12/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

MADRID

MADRID

Servicio de Hematología

Medicamentos

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

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

Experimental

Calquence 100 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Experimental

Chlorambucil 2 mg tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01AA02 - CLORAMBUCILO
Principios Activos: N/A

Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01XC15 - OBINUTUZUMAB
Principios Activos: N/A

Huérfano

Experimental

Sin resultados

A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP 196 in Combination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	323
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-509348-84-00 (CTIS)

Protocol Code
ACE-CL-007

Transitioned 2014-005582-73

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

Investigated Disease
Chronic Lymphocytic Leukemia

Scientific Title
A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP 196 in Combination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated

Chronic Lymphocytic Leukemia

Rationale

Not provided

Main Objective

To evaluate the efficacy of obinutuzumab in combination with chlorambucil (Arm A) compared with acalabrutinib in combination with obinutuzumab (Arm B), based on IRC assessment of PFS per IWCLL 2008 criteria, in subjects with previously untreated CLL.

Primary Endpoints

The primary endpoint of the study is PFS as assessed by IRC review per IWCLL 2008 criteria. The primary analysis is a comparison of PFS between Arm A and Arm B.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of Arm A versus acalabrutinib monotherapy based on IRC assessment of PFS per IWCLL 2008 criteria. To compare Arm A versus Arm B and Arm A versus Arm C in terms of: IRC-assessed objective response rate (ORR) per IWCLL 2008 criteria; Time to next treatment (TTNT) (defined as the time from randomization to institution of non-protocol specified treatment for CLL); Overall survival (OS);

Secondary Endpoints

"Efficacy: The first secondary endpoint is a comparison of IRC-assessed PFS between Arm A and Arm C. Other secondary endpoints are as follows and compare Arm A versus Arm B and Arm A versus Arm C OS. Safety: Frequency, severity, and relatedness of adverse events. Frequency of adverse events requiring discontinuation of study drug or dose reductions. Change in laboratory assessments. "
Efficacy: The first secondary endpoint is a comparison of IRC-assessed PFS between Arm A and Arm C. Other secondary endpoints are as follows and compare Arm A versus Arm B and Arm A versus Arm C OS. Safety: Frequency, severity, and relatedness of adverse events. Frequency of adverse events requiring discontinuation of study drug or dose reductions. Change in laboratory assessments.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

" Men and women 65 years of age, or > 18 and < 65 years of age provided that they meet at least one of the following criteria: o Creatinine clearance 30 to 69 mL/min using the Cockcroft-Gault equation. o A score higher than 6 on the Cumulative Illness Rating Scale-Geriatric (CIRS-G). ECOG performance status of 0, 1, or 2. Diagnosis of CD20+ CLL that meets published diagnostic criteria (Hallek 2008) Active disease meeting 1 of the following IWCLL 2008 criteria for requiring treatment: o Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia (hemoglobin < 10 g/dL) and/or thrombocytopenia (platelets < 100,000/L). o Massive (ie, 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. o Massive nodes (ie, 10 cm in the longest diameter), progressive, or symptomatic lymphadenopathy. o Progressive lymphocytosis with an increase of > 50% over a 2-month period or a lymphocyte doubling time (LDT) of < 6 months. 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Calendar

(Last Update: 17/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/11/2015	31/03/2016	Not aported	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
07/12/2016	Not aported	Not aported	30/09/2025	04/09/2026

Sponsor

Acerta Pharma B.V. Netherlands

Kloosterstraat 9

Contact Person

Carla Hartman

0031615465931

carla.hartman@acerta-pharma.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Fundacio de Gestio Sanitaria Hospital de la Santa Creu i Sant Pau

C/ Sant Quintí, 77-79. Planta 1a. Despacho 95 08041 Barcelona

ceimsantpau@santpau.cat

935537813

Sites

Closed (13/06/2016)

CLINICA UNIVERSIDAD DE NAVARRA

PAMPLONA/IRUÑA

NAVARRA

Servicio de Hematología

Closed (25/02/2026)

HOSPITAL DE LA SANTA CREU I SANT PAU

BARCELONA

BARCELONA

Servicio de Hematología

Closed (30/03/2017)

HOSPITAL GENERAL UNIVERSITARIO J.M. MORALES MESEGUER

MURCIA

MURCIA

Servicio de Hematología

Closed (15/03/2017)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

MADRID

MADRID

Servicio de Hematología

Closed (09/02/2026)

HOSPITAL UNIVERSITARIO INFANTA LEONOR (*)

MADRID

MADRID

Servicio de Hematología

Closed (14/06/2022)

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SANTANDER

CANTABRIA

Servicio de Hematología

Closed (30/01/2026)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

MAJADAHONDA

MADRID

Servicio de Hematología

Closed (12/12/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

MADRID

MADRID

Servicio de Hematología

Medication

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

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

Experimental

Calquence 100 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Experimental

Chlorambucil 2 mg tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01AA02 - CLORAMBUCILO
Active Principles: N/A

Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01XC15 - OBINUTUZUMAB
Active Principles: N/A

Orphan
Experimental

No results